

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



SARE Reporting for Blood and Blood Components

SoHO Standards Section, Intergovernmental Committees and Networks
Department (ICND)
EDQM, Council of Europe

2025 SARE Exercise (2024 data)



DATA COLLECTED from 28* Countries:






AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LT, LU, NL, NO, PL, PT, RO, SK, SI, ES, SE and UK (Northern Ireland)

- 2022 SARE exercise: 30 reporting countries
- 2023 SARE exercise: 30 reporting countries
- 2024 SARE exercise: 30 reporting countries

*25 Member States + 3 Non-Member States



Note: HU, LI and MT didn't submit data for this current exercise

- Activity Dataset 
- SAR (IL 2-3) in Recipients 
- SAE 
- SAR in Donors 
- Annexes 

Highlights 2025

2025 SARE Exercise (2024 data)

28 Countries
25 EU MS plus Iceland, Norway and the UK (Northern Ireland)

3 190 reporting establishments

1 360 SAR (IL 2-3) (n=25) ↓ 5%

8.3 SAR (IL 2-3) per 100 000 units transfused
[median: 5.2] ↑ (+1.5)

- Reaction profile unchanged:
 - FNHTR (most frequent)
 - Anaphylaxis/hypersensitivity
 - TACO (increasing trend)
- Platelets continue to show the highest SAR incidence
- 14 TTIs (IL 2-3) (6 less than in 2023)

4 764 SAE (n=25) ↑ 1.08%
(Driven by RBC's data)

19.5 SAE per 100 000 units processed
(Excluding RQ, median: 6.4)

- Root cause pattern shifted: component defect (60%) overlook human error (14%)
(Excluding RQ, human error remains the leading cause (28%))

Haemovigilance 2025 Highlights

Donation activity rate (median):
31.8 WB collections per 1 000 pop. ↓ 8%
2.5 apheresis collections per 1 000 pop.

-2.6 M units of plasma issued (n=23) ↓ 1.3%

-16.5 M units transfused (n=23)

- 3 M patients transfused (n=21)

RBC, platelet and plasma transfusion rates pmp (median)

Year	RBC	Platelets	Plasma	MTCO
2021	25	15	10	5
2022	27	16	11	6
2023	21	14	9	4
2024	11	12	8	3

11 fatalities (IL 2-3) (n=5)

2 260 SAR in donors (n=25) ↓ 35%*
(Driven primarily by FTA's scope update)

4 fatalities in donors (One ever reported)

(infographic made in CANVA)

Activity Dataset

- Total Number of Units Issued (*sum of number of units for each type of blood component*)
- Total Number of Units Transfused (*sum of number of units for each type of blood component*)
- Total Number of Recipients Transfused (*regardless of type of blood component*)

- Total Number of Units Processed

- Total Number of Whole Blood Collections
- Total Number of Apheresis Collections

Activity Dataset

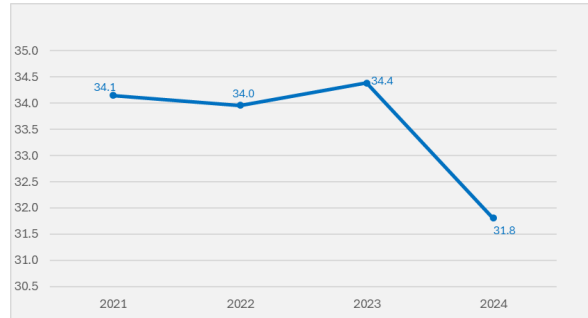
- Annual trends (2021 – 2024)
- Geographic distribution
- Overview of volume of activity
- Country-specific trends (2023 vs. 2024)



Annual Trends **Whole Blood** Donation/Collection Rate (median)

2025 SARE Exercise (2024 data)

(per 1 000 population)



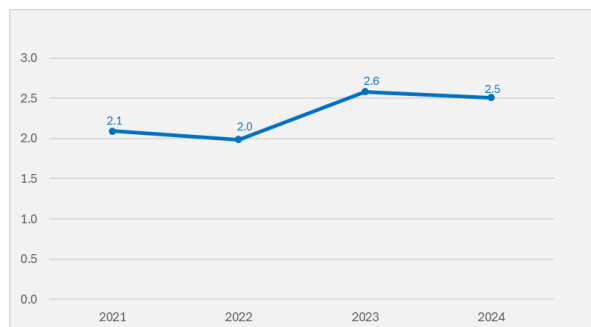
n	28	26	26	26

population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Annual Trends **Apheresis** Donation Rate (median)

2025 SARE Exercise (2024 data)

(per 1 000 population)



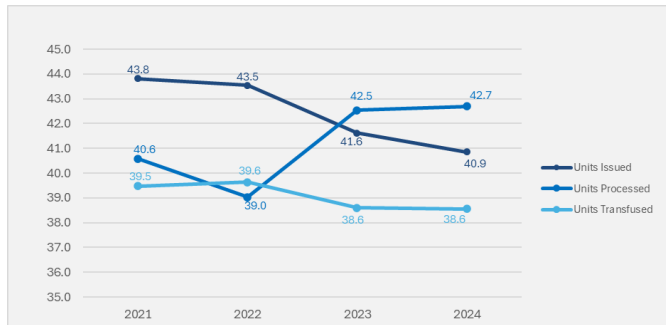
n	2021	2022	2023	2024
n	28	26	25	25

population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Annual Trends Rates of units issued, transfused and processed (median)

2025 SARE Exercise (2024 data)

(per 1 000 population)



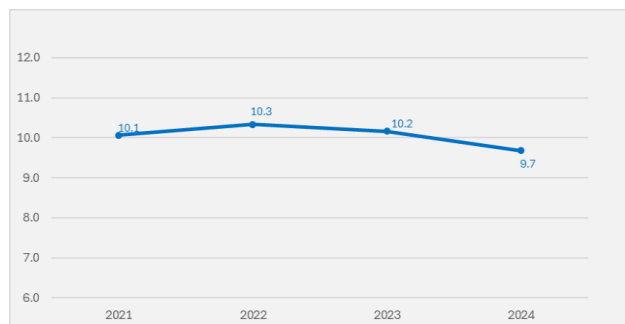
n(issued)	30	30	30	28
n(processed)	28	27	26	28
n(transfused)	26	24	23	23

population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Annual Trends Rate of Recipients transfused (median) 2025 SARE Exercise (2024 data)

(per 1 000 population)

(regardless of type of BC)



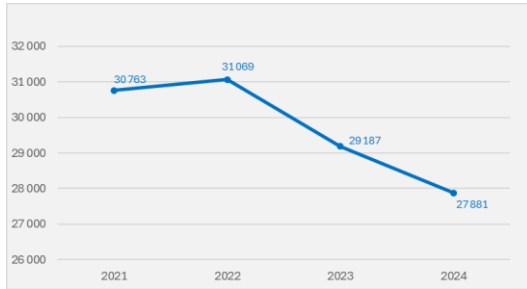
n	16	18	17	17

population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Annual Trends Transfusion Rate (median)
by Type of BC **pmp**

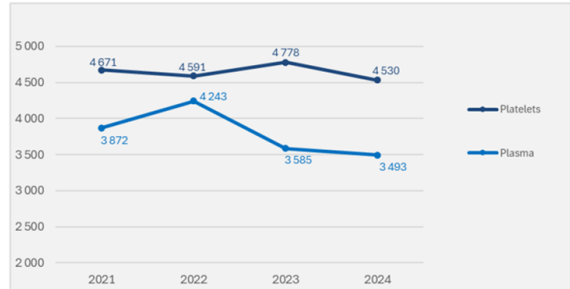
2025 SARE Exercise (2024 data)

Red Blood Cells (RBC)



n	2021	2022	2023	2024
n	25	24	23	23

Platelets and Plasma



n(platelets)	26	24	23	23
n(plasma)	26	23	23	24

BC= blood component
pmp= per 1 million population

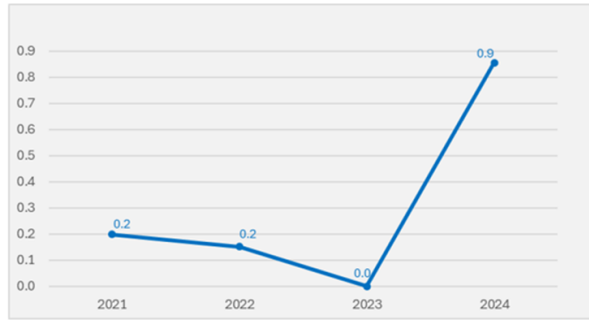
population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Note: for plasma, n includes countries that reported zero units transfused

Annual Trends Transfusion Rate (median)
by Type of BC **pmp**

2025 SARE Exercise (2024 data)

Whole Blood



n	21	25	22	19

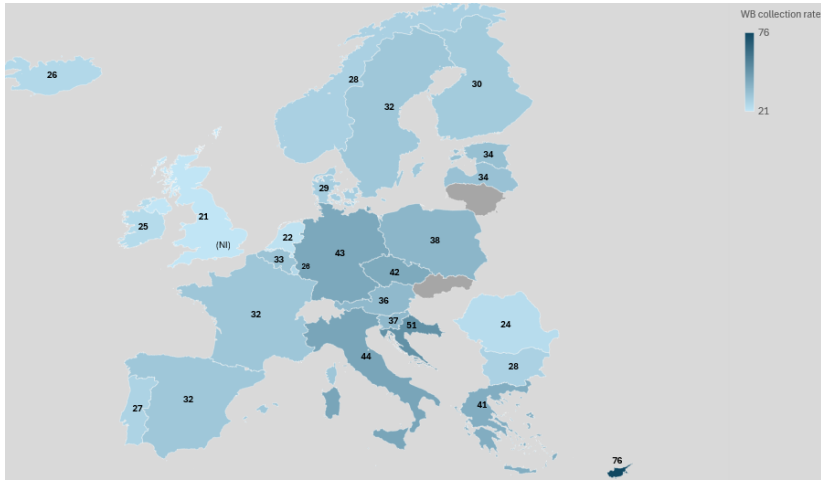
population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Note: n includes countries that reported zero whole blood units transfused

WB Collection Rates

2025 SARE Exercise (2024 data)

(per 1 000 population)



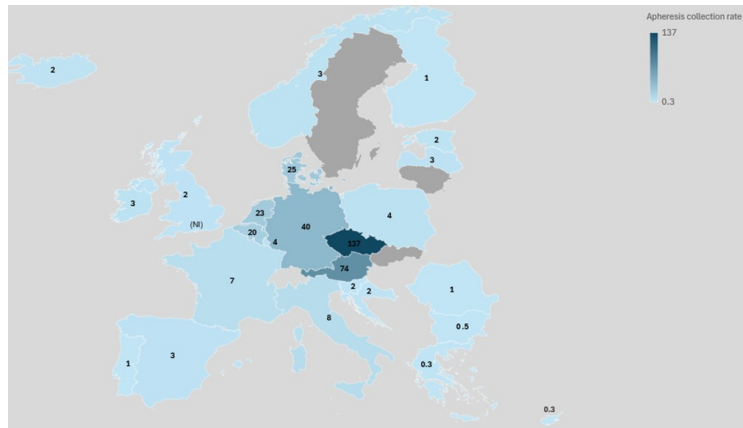
population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Note: LU and SK reported N/A

Apheresis Collection Rates

2025 SARE Exercise (2024 data)

(per 1 000 population)



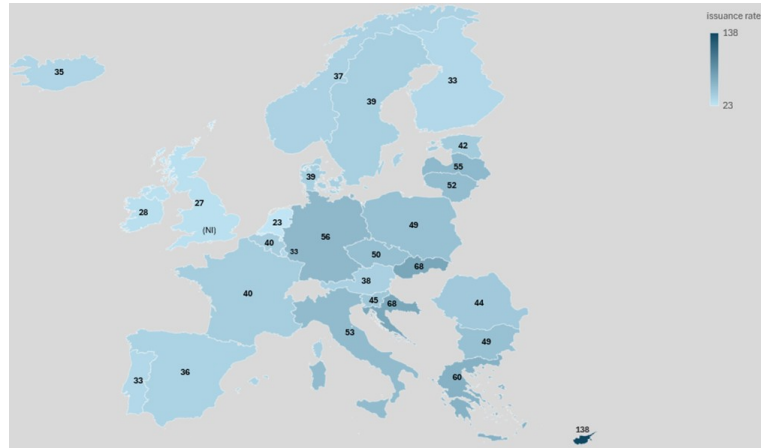
population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Note: LU, SK and SE reported N/A

Issuance Rates of blood/BC units

2025 SARE Exercise (2024 data)

(per 1 000 population)

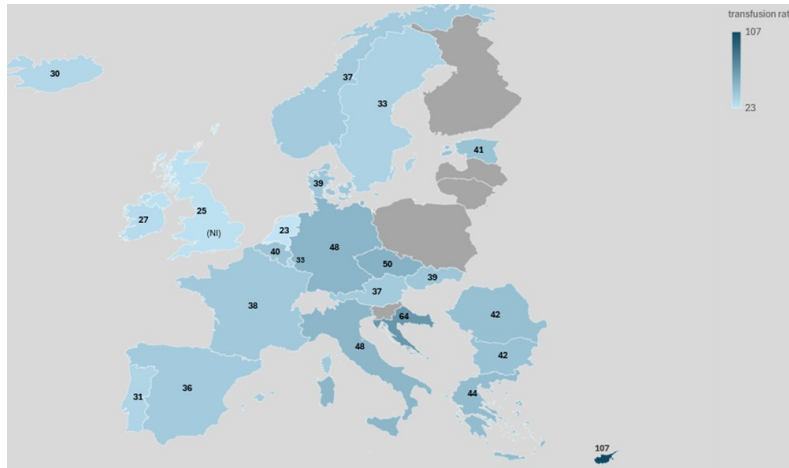


population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Transfusion Rates of blood/BC units

2025 SARE Exercise (2024 data)

(per 1 000 population)



population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

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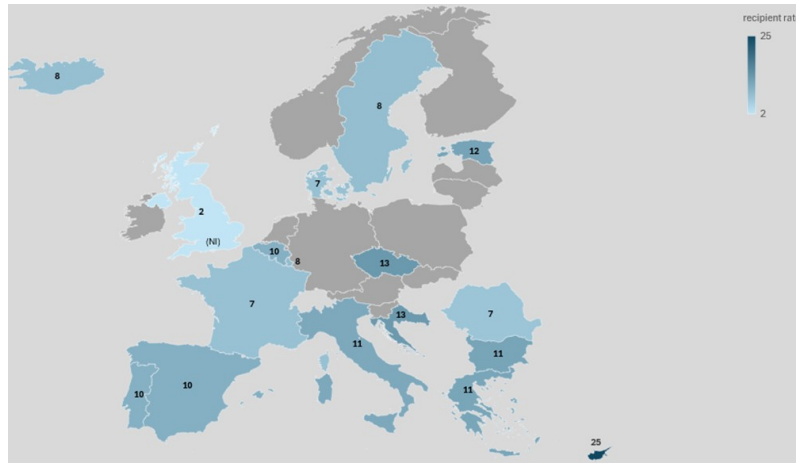
Note1: new rate reported for SK; significant increase for RO in comparison with 2023 (rate 23)

Note2: FI, LV, LT, PL and SI reported N/A

Recipient Rate

2025 SARE Exercise (2024 data)

(per 1 000 population) (regardless of type of BC)



population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

Note1: new rate reported for RO

Note2: AT, FI, DE, IE, LV, LT, NL, NO, PL, SK and SI reported N/A

Comment NL: "66/79 hospitals provided numbers of recipients per type of blood component. Fewer hospitals 61/79 = 77% (see general numbers) provided total number of recipients (irrespective of the type of blood component); that is why we do not give a total for this."

Activity Dataset by Type of BC

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Total Number of Units Issued	2023	2024	% Change
RBC	15 933 863	15 413 314	-3
Platelets	2 561 256	2 430 261	-5
Plasma	2 324 231	2 619 750	+13
WB	4 669	3 894	-17
n (RBC)	30	28	
n (Platelets)	30	28	
n (Plasma)	30 (including 2 reporting zero)	28 (including 2 reporting zero)	
n (WB)	25 (including 12 reporting zero)	22 (including 7 reporting zero)	

Total Number of Units Transfused	2023	2024	% Change
RBC	12 565 950	12 758 561	+2
Platelets	1 936 030	1 992 202	+3
Plasma	1 707 318	1 724 288	+1
WB	3 936	3 361	-15
n (RBC)	23	23	
n (Platelets)	23	23	
n (Plasma)	23 (including 2 reporting zero)	24 (including 2 reporting zero)	
n (WB)	22 (including 12 reporting zero)	19 (including 7 reporting zero)	

Total Number of Recipients transfused	2023	2024	% Change
RBC	2 202 858	2 320 512	+5
Platelets	266 131	294 558	+11
Plasma	210 292	249 752	+19
WB	1 480	1 547	+5
n (RBC)	18	18	
n (Platelets)	18	18	
n (Plasma)	18 (including 2 reporting zero)	19 (including 2 reporting zero)	
n (WB)	18 (including 12 reporting zero)	17 (including 7 reporting zero)	

n = number of countries reporting

Transfusion Rates (median) **pmp** by Type of BC

2025 SARE Exercise (2024 data)

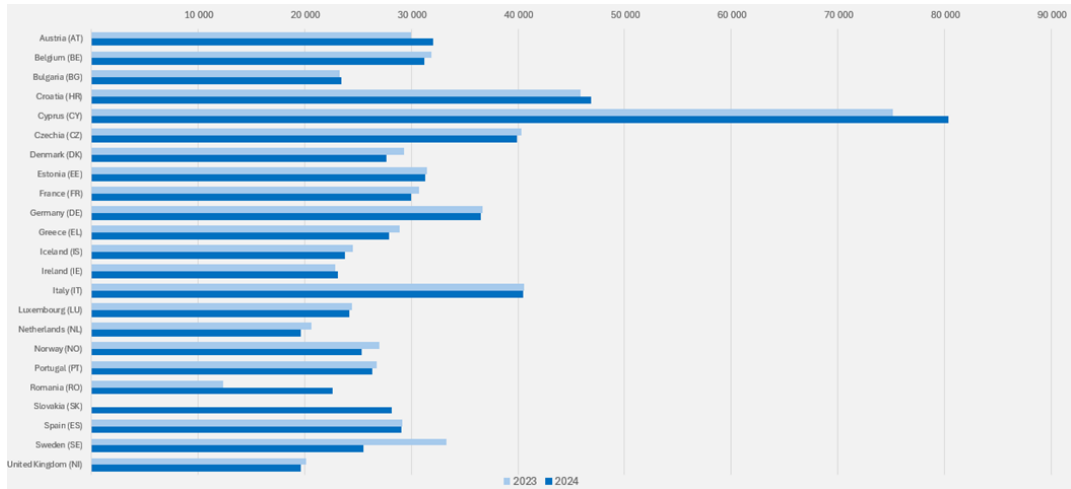
comparative data 2023 - 2024

Type of BC	2023 (median rate pmp)	2024 (median rate pmp)
RBC	29 187	27 881
Platelets	4 778	4 530
Plasma	3 585	3 493
Whole Blood	0.0	0.9

Transfusion Rates - RBC

2025 SARE Exercise (2024 data)

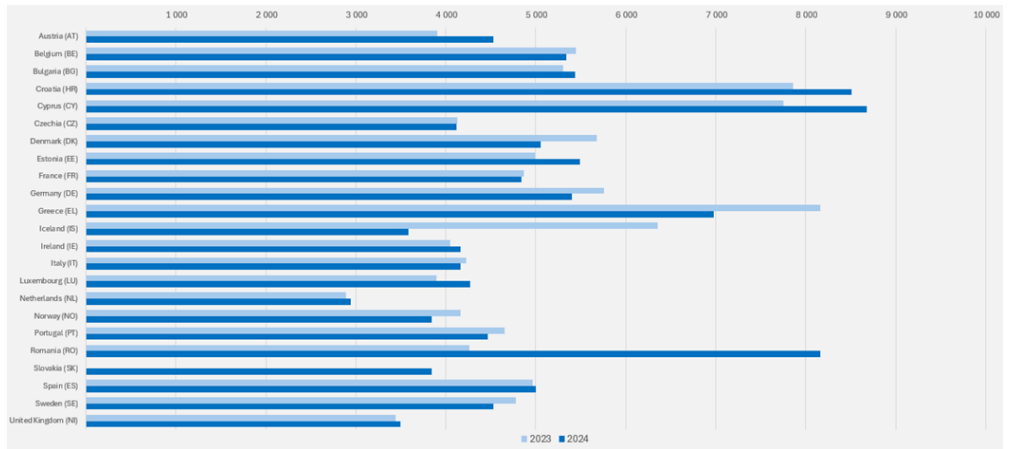
(pmp); comparative data 2023 - 2024



Transfusion Rates - Platelets

2025 SARE Exercise (2024 data)

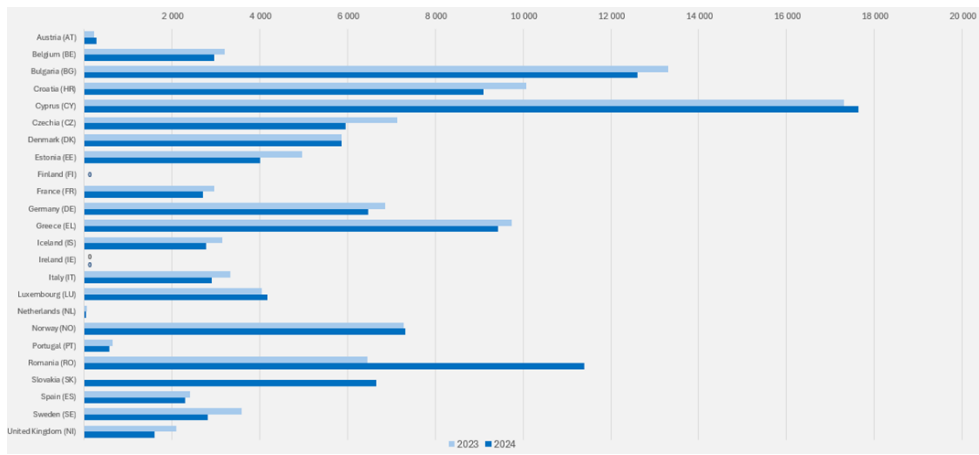
(pmp); comparative data 2023 - 2024



Transfusion Rates - Plasma

2025 SARE Exercise (2024 data)

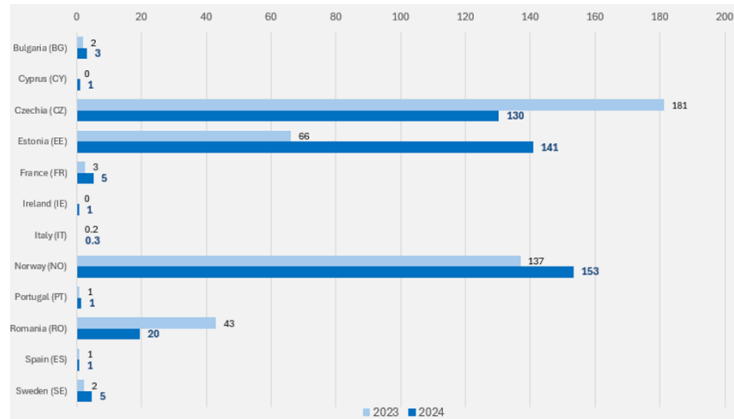
(pmp); comparative data 2023 - 2024



Transfusion Rates – Whole Blood

2025 SARE Exercise (2024 data)

(pmp); comparative data 2023 - 2024



Comment CY: “We do not transfuse whole blood units. This year, however, there was one case of autologous blood transfusion (the blood was collected, tested and then transfused).”

Note: in 2023, AT, HR, CY, DE, EL, IS, IE, LV, LI, LU, NL and UK(NI) reported 0 units and consequently a zero rate (not shown above). In 2024, AT, BE, HR, CY, EL, IS, NL and UK(NI) reported 0 units of WB transfused and consequently a zero rate (not shown above).

Serious Adverse Reactions (in Recipients)

27 Countries:

AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IE, IT, LV, LT, LU, NL, NO, PL, PT, RO, SK, SI,
ES, SE and UK(NI)
(No SAR from IS)

Denominator used:

- Total Number of Units Transfused (*sum of number of units for each type of BC*)



SAR (IL 2-3) (Mandatory)

- Annual trends (2021 – 2024)
- Geographic distribution

- Annual trends (2021 – 2024) by type of BC
- Country specific trends (2023 vs. 2024) by type of BC
- Overview of SAR and fatalities by type of BC

- Annual trends (2021 – 2024) by type of reaction
- Overview of SAR and fatalities by type of reaction

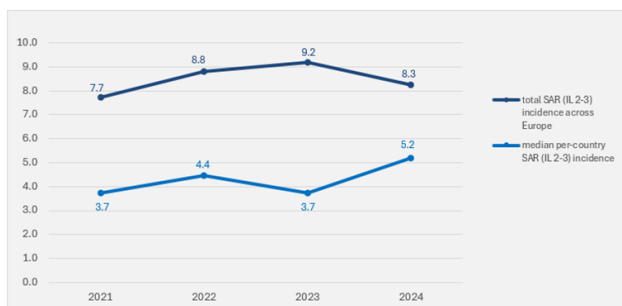
- Fatalities examples



Annual Trends SAR (IL 2-3) Incidence (total and median)

2025 SARE Exercise (2024 data)

(per 100 000 units transfused)



n	2021	2022	2023	2024
n	26	24	24	23

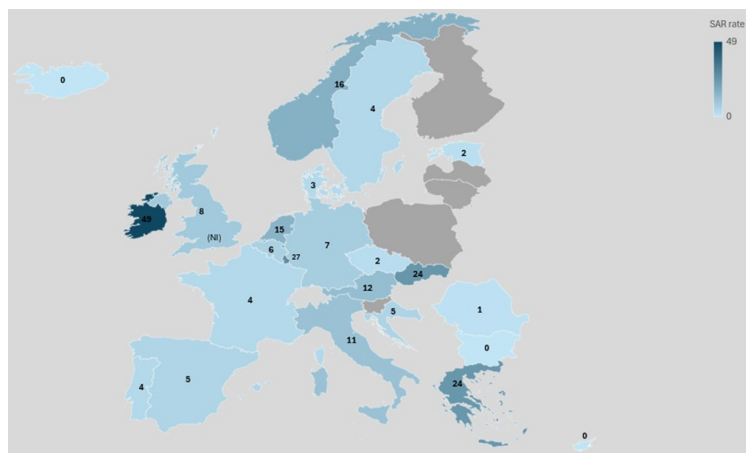
Note1: two complementary metrics: (1) the total SAR (IL 2–3) incidence per 100 000 units of blood/BC transfused, and (2) the median of country-specific SAR (IL 2–3) incidence rates (per 100 000 units transfused) across all reporting countries. Total SAR (IL 2-3) is calculated using all reported cases as the numerator and the sum of all reported units transfused (including countries reporting zero SAR) as the denominator. Countries not reporting denominator data but reporting SAR contribute to the numerator but not the denominator. Please refer to the denominator completeness table (Annex) for coverage details.

Note2: only countries (n) that reported both SAR (IL 2-3) cases (including zero) and the corresponding number of units of blood/BC transfused were included in the median per-country incidence calculations

SAR (IL 2-3) Incidence rates

2025 SARE Exercise (2024 data)

(per 100 000 units transfused)



Note1: the following countries reported SAR- FI (13), LV (1), LT (1), PL (73) and SI (13) but didn't provide number of units transfused so incidence couldn't be calculated

Note2: significant increase for LU and IE in comparison with 2023 (rate 0 and 19, respectively)

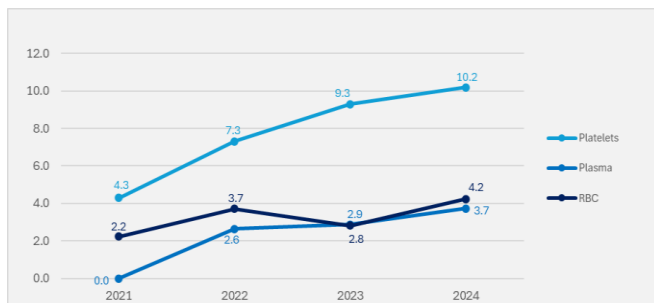
moderate increase for NL, HR and SE (rate 12, 3 and 2 respectively)

rates decreased for AT, IT, PT and ES

Annual Trends Median SAR (IL 2-3) Incidence per country by Type of BC

2025 SARE Exercise (2024 data)

(per 100 000 units transfused)



n(platelets)	26	24	23	23
n(plasma)	25	21	21	22
n(RBC)	25	24	23	23

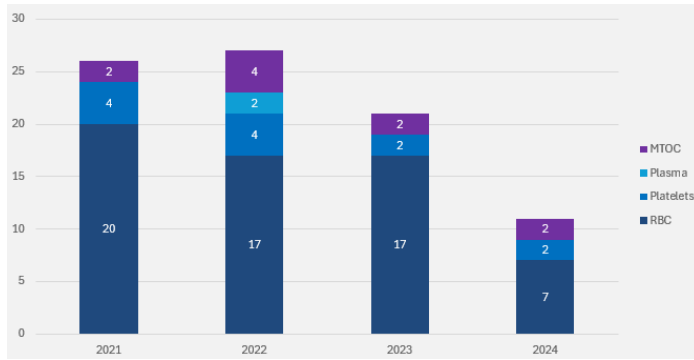
Note1: only countries that reported both SAR (IL 2-3) cases (including zero) and the corresponding number of units transfused per BC were included in the median per-country incidence calculations

Note 2: median SAR incidence in WB is not shown above as only one country reported throughout the period (2021: 2 cases; 2022: 0; 2023: 1 case; 2024: 2 cases).

Annual Trends Fatalities (IL 2-3) by Type of BC

2025 SARE Exercise (2024 data)

Absolute numbers



MTOC = more than one blood component transfused

SAR (IL 2-3) Incidence rates by

2025 SARE Exercise (2024 data)

Type of BC

(per 100 000 units transfused)

comparative data 2023 - 2024

Potential real-concern signals

True improvements

* denominator missing

Country	RBC			Platelets			Plasma		
	2023	2024	Absolute change	2023	2024	Absolute change	2023	2024	Absolute change
Austria (AT)	20	12	-8	22	12	-10	48	0	-48
Belgium (BE)	4	5	+1	12	13	+1	5	6	+1
Bulgaria (BG)	1	0	-1	0	0	0	0	0	0
Croatia (HR)	3	5	+2	3	9	+6	0	3	+3
Czechia (CZ)	2	2	0	2	0	-2	10	5	-5
Denmark (DK)	2	1	-1	6	7	+1	3	6	+3
Estonia (EE)	0	2	+2	0	0	0	0	0	0
France (FR)	2	3	+1	9	8	-1	14	10	-4
Germany (DE)	5	6	+1	11	15	+4	5	6	+1
Greece (EL)	26	12	-14	26	58	+32	20	36	+16
Ireland (IE)	18	43	+25	23	79	+56	-	-	-
Italy (IT)	11	8	-3	40	35	-5	11	8	-3
Luxembourg (LU)	0	30	+30	0	34	+34	0	0	0
Netherlands (NL)	9	14	+5	17	17	0	0	0	0
Norway (NO)	9	4	-5	13	28	+15	7	7	0
Portugal (PT)	5	3	-2	12	6	-6	0	0	0
Romania (RO)	1	1	0	1	1	0	1	1	0
Slovakia (SK)	*	19	-	*	58	-	*	28	-
Spain (ES)	6	4	-2	12	10	-2	12	5	-7
Sweden (SE)	2	4	+2	4	2	-2	0	7	+7
United Kingdom (NI)	23	5	-18	45	30	-15	50	0	-50

Note 1: CY and IS reported zero SAR across the different types of BC in both 2023 and 2024 (not shown above).

Note 2: SAR incidence rates in WB not shown above (2023 (IT): 1 SAR reported; 2024 (NO): 2 SAR reported).

Note 3: *in 2023, SK reported N/A for number of units transfused so incidence could not be calculated.

Note 4: highlighted in red are changes that represent a potential real concern. These countries show multiple SARs (not just 1–2), large transfusion denominators (so rates are stable), sharp increases beyond what small-number variation can explain. Highlighted in green are true improvements not strongly influenced by small denominators or low SAR counts.

SAR (IL 2-3) by Type of BC

2025 SARE Exercise (2024 data)

(for countries which also reported SAR but are missing denominator data)

comparative data 2023 - 2024

RBC

Country	2023	2024	Absolute change
Finland (FI)	4	7	+3
Latvia (LV)	1	0	-1
Lithuania (LT)	0	1	+1
Poland (PL)	53	54	+1
Slovenia (SI)	6	6	0

Platelets

Country	2023	2024	Absolute change
Finland (FI)	0	6	+6
Latvia (LV)	0	0	0
Lithuania (LT)	0	0	0
Poland (PL)	11	6	-5
Slovenia (SI)	3	4	+1

Plasma

Country	2023	2024	Absolute change
Finland (FI)	0	-	-
Latvia (LV)	1	0	-1
Lithuania (LT)	0	0	0
Poland (PL)	9	9	0
Slovenia (SI)	1	3	+2

Total SAR (IL 2-3) and Fatalities (IL 2-3) by Type of BC

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Total Number of SAR (IL 2-3)	2023	2024	% Change
RBC	972	821	-16
Platelets	312	334	+7
Plasma	143	142	-1
MTOC	62	61	-2
WB	1	2	<i>(absolute change +1)</i>
TOTAL	1 490	1 360	-9

n (RBC)	24	24
n (Platelets)	21	21
n (Plasma)	16	15
n (MTOC)	12	10
n (WB)	1	1

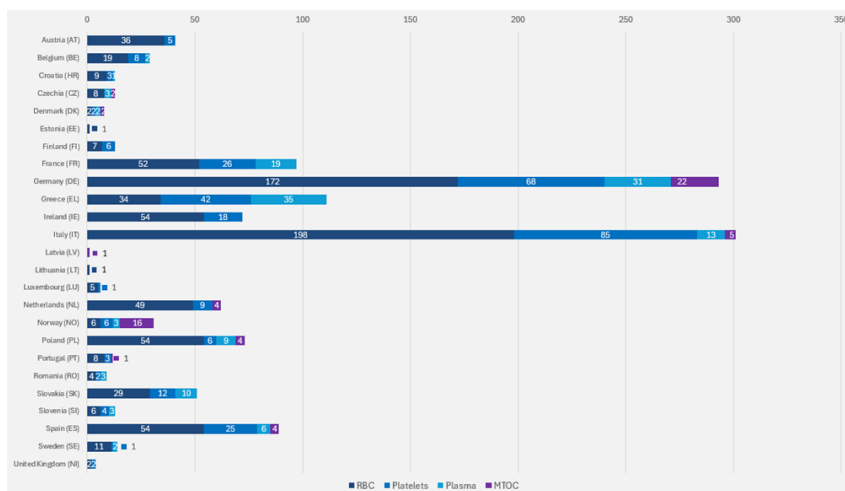
Total Number of Fatalities (IL 2-3)	2023	2024	Absolute Change
RBC	17	7	-10
Platelets	2	2	0
Plasma	0	0	0
MTOC	2	2	0
WB	0	0	0
TOTAL	21	11	-10

n (RBC)	9	4
n (Platelets)	2	1
n (Plasma)	0	0
n (MTOC)	1	2
n (WB)	0	0

Total SAR (IL 2-3) by Type of BC

2025 SARE Exercise (2024 data)

Absolute numbers



Note1: also 2 SAR for Whole Blood from NO were reported
 Note2: BG, CY and IS reported zero SAR (not shown above)

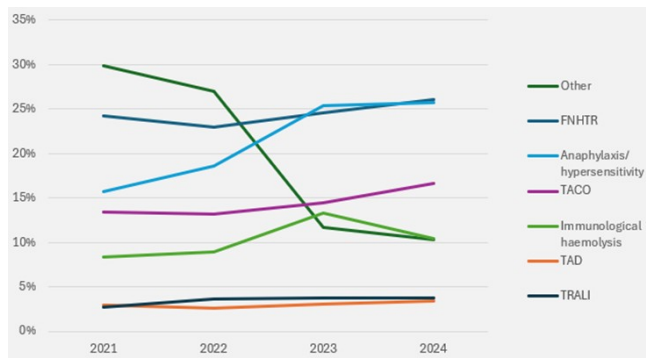
Immunologically related SAR	Cardiovascular and metabolic problems	Transfusion-transmitted infection (TTI)
<ul style="list-style-type: none"> • Transfusion-related acute lung injury (TRALI) • Anaphylaxis/hypersensitivity • Febrile non-haemolytic transfusion reaction (FNHTR) • Immunological haemolysis (due to ABO incompatibility/due to other alloantibody) • Post-transfusion purpura (PTP) • Transfusion-associated graft-versus-host disease (Ta-GvHD) 	<ul style="list-style-type: none"> • Transfusion-associated cardiovascular overload (TACO) • Hypotensive transfusion reaction • Transfusion-associated dyspnoea (TAD) 	<ul style="list-style-type: none"> • Bacterial (TTBI) • Viral (TTVI) <ul style="list-style-type: none"> ○ HBV, HCV, HIV-1/2, other • Parasitical (TTPI) <ul style="list-style-type: none"> ○ malaria, other • Fungal (TTFI) • Prion (TTPRI)
<p>Non-immunological haemolysis</p> <p style="text-align: center;"><i>Other (reactions which do not meet the criteria for a defined category)</i></p>		

Annual Trends SAR (IL 2-3) by main Types of Reaction

2025 SARE Exercise (2024 data)

Percentage (%) of total SAR (IL 2-3)

Main Types of Reaction	2021	2022	2023	2024
Other	29.9	27.0	11.7	10.4
FNHTR	24.2	23.0	24.6	26.1
Anaphylaxis/ hypersensitivity	15.7	18.6	25.4	25.7
TACO	13.4	13.2	14.4	16.7
Immunological haemolysis	8.4	9.0	13.3	10.4
TAD	3.0	2.6	3.1	3.5
TRALI	2.7	3.6	3.8	3.8



Annual Trends Fatalities (IL 2-3) by Type of Reaction

2025 SARE Exercise (2024 data)

Absolute numbers

Type of Reaction	2021	2022	2023	2024	TOTAL
Immunological haemolysis	11	9	9	3	32
TACO	8	4	4	2	18
TRALI	2	9	3	1	15
TTBI	3	4	3	1	11
Other	1	0	2	1	4
Anaphylaxis/ hypersensitivity	0	1	0	2	3
Hypotensive transfusion reaction	0	0	0	1	1
TOTAL	25	27	21	11	-
% of total SAR (IL 2-3)	1.81	1.78	1.40	0.81	-

SAR (IL 2-3) by Type of Reaction

2025 SARE Exercise (2024 data)

Absolute numbers;
comparative data 2023 - 2024

Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
FNHTR	2	355 (-12)
Anaphylaxis/ hypersensitivity	1	350 (-28)
TACO	3	227 (+12)
Immunological haemolysis	4	142 (-96)
Other	5	141 (-34)
TRALI	6	52 (-4)
TAD	7	47 (+1)
Hypotensive transfusion reaction	10	16 (+2)
Non-immunological haemolysis	8	14 (-2)
TTVI	12	8 (+4)
TTBI	9	6 (-9)
PTP	11	2 (-3)
TTPI	13	0 (-1)
TOTAL	-	1 360 (-130)

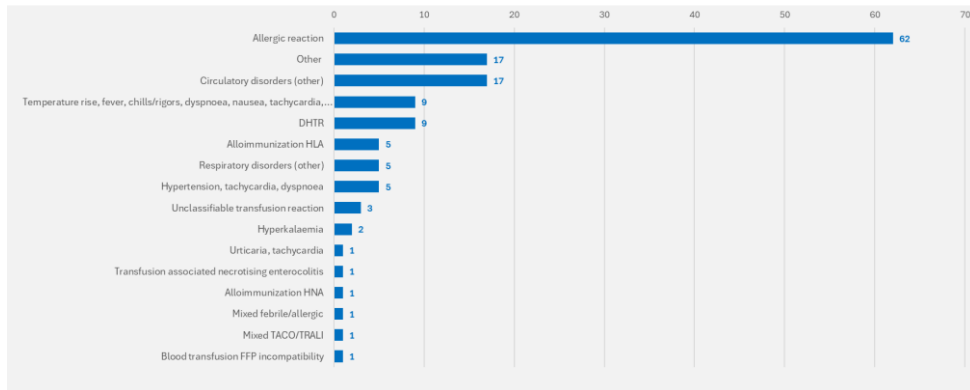
Note: for both 2023 and 2024, no data was reported for the following types of reaction: Transfusion associated graft versus host disease and Transfusion-transmitted fungal and prion infection

Comment DE: *“Please note that six cases listed in the category “Immunological haemolysis due to other alloantibody” refer to Autoimmunhaemolysis triggered by the transfusion (Imputability level 2: 4 cases; Imputability level 3: 2 cases).”*

Distribution of SAR (IL 2-3) classified as

2025 SARE Exercise (2024 data)

'Other' Absolute numbers



Comment DE: “Each year a couple amount of reactions are reported with the term “other”. Most of these reactions are symptoms due to another medical condition which coincidentally happened in a timely relationship to the transfusion. These are assessed as unlikely and therefore not reported. In some cases the reported symptoms might be attributable to allergic type reactions or febrile reactions but are not diagnosed as such by the reporters. These cases are assessed as possible and therefore reported.”

SAR (IL 2-3) by Type of Reaction and by Type of BC (excludes fatalities (IL 2-3))

2025 SARE Exercise (2024 data)

Absolute numbers;
comparative data 2023 - 2024

Top 5 Reaction Types	WB			RBC			Platelets		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
Anaphylaxis/hypersensitivity	0	1	+1	133	100	-33	140	135	-5
FNHTR	0	0	0	276	224	-52	71	110	+39
TACO	1	0	-1	170	200	+30	12	10	-2
Immunological haemolysis	0	0	0	a) 65 b) 108	a) 62 b) 68	a) -3 b) -40	a) 1 b) 10	a) 3 b) 1	a) +2 b) -9
Other	0	1	+1	103	83	-20	52	34	-18
n (Anaphylaxis/hypersensitivity)	0	1		15	16		17	19	
n (FNHTR)	0	0		11	15		6	8	
n (TACO)	1	0		20	19		7	7	
n (Immunological haemolysis)	0	0		a) 14 b) 20	a) 11 b) 17		a) 1 b) 2	a) 3 b) 1	
n (Other)	0	1		10	14		7	7	

Immunological Haemolysis
a) due to ABO incompatibility
b) due to other alloantibody

Comment DE: “Please note that seven cases listed in the category “Immunological haemolysis due to other alloantibody” refer to Autoimmunhaemolysis triggered by the transfusion (Imputability level 1: 1 case; Imputability level 2: 4 cases; Imputability level 3: 2 cases).”

“Each year a couple amount of reactions are reported with the term “other”. Most of these reactions are symptoms due to another medical condition which coincidentally happened in a timely relationship to the transfusion. These are assessed as unlikely and therefore not reported. In some cases the reported symptoms might be attributable to allergic type reactions or febrile reactions but are not diagnosed as such by the reporters. These cases are assessed as possible and therefore reported.”

SAR (IL 2-3) by Type of Reaction and by Type of BC cont. (excludes fatalities (IL 2-3))

2025 SARE Exercise (2024 data)

Absolute numbers;
comparative data 2023 - 2024

Top 5 Reaction Types	Plasma			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change
Anaphylaxis/hypersensitivity	89	91	+2	16	21	+5
FNHTR	15	14	-1	5	7	+2
TACO	9	6	-3	19	9	-10
Immunological haemolysis	a) 3	a) 1	-2	b) 2	b) 4	+2
Other	14	17	+3	4	5	+1
n (Anaphylaxis/hypersensitivity)	14	14		6	6	
n (FNHTR)	4	3		3	4	
n (TACO)	5	4		7	6	
n (Immunological haemolysis)	a) 1	a) 1		b) 2	b) 1	
n (Other)	4	3		4	3	

Immunological Haemolysis
a) due to ABO incompatibility
b) due to other alloantibody

Note: Also, for Whole Blood, in 2024, 1 anaphylaxis/hypersensitivity, 1 Other: Hyperkalemia (vs 2023: 1 TACO)

Comment NO: (2 Whole Blood SAR) *“The hyperkalemic reaction was life-threatening and led to a cardiac arrest. This incidence will be reported on in a scientific publication, hopefully within a month or two. The anaphylactic episode will also be mentioned in this publication.”*

SAR (IL 2-3) - TTI

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Type of TTI	2023	2024	Absolute Change
TTBI	15	6	-9
TTVI	4	8	+4
TTPI	1	0	-1
TOTAL	20	14	-6

n (TTBI)	7	4
n (TTVI)	3	3
n (TTPI)	1	0

Type of TTI	RBC			Platelets			Plasma			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
TTBI	7	1	-6	8	5	-3						
TTVI	3	2	-1	0	5	+5	1	0	-1	0	1	+1
TTPI	1	0	-1									
TOTAL	11	3	-8	8	10	+2	1	0	-1	0	1	+1

TT- Transfusion Transmitted

Note 1: zero TTFI and TTPRI cases reported in both 2023 and 2024.

Note 2: zero TTIs reported in WB in both 2023 and 2024.

SAR (IL 2-3) - TTBI

2025 SARE Exercise (2024 data)

TTBI

Country (#SAR)	RBC	Platelets
France (1)		(1) <i>Staphylococcus ureilyticus</i>
Germany (3)	(1) <i>E. coli</i>	(2) <i>Bacillus cereus</i>
Greece (1)		(1) N/A
Spain (1)		(1) <i>E. coli</i>

TTVI

Country (#SAR)	RBC	Platelets	MTOC
Finland (4)	(1) Other: HEV	(3) Other: HEV	
France (1)		(1) Parvo-B19	
Germany (3)	(1) Parvo-B19	(1) Parvo-B19	(1) Parvo-B19



The exact infectious pathogen was provided for 5 (83%) out of 6 SAR- TTBI (in 2023: 47%)

Note: Spain platelets case occurred in 2023, but investigation finalized in 2024

Total Fatalities (IL 2-3) by Type of Reaction, 2025 SARE Exercise (2024 data) Type of BC and Country

Absolute numbers

Fatalities (IL 2-3) = 11

5 Countries Reporting: BE, FI, FR, DE, NO

Type of Reaction	# IL 2	# IL 3
TACO	2	
Anaphylaxis/ hypersensitivity	2	
Immunological haemolysis due to ABO incompatibility		2
Other		1
TTBI		1
Immunological haemolysis due to other alloantibody		1
TRALI	1	
Hypotensive transfusion reaction	1	
TOTAL	6	5

Country (#)	RBC	Platelets	MTOC
Belgium (1)	1		
Finland (1)	1		
France (4)	2	2	
Germany (4)	3		1
Norway (1)			1

Fatalities (IL 2-3) by Type of Reaction and by Type of BC

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Type of Reaction	RBC			Platelets			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
Immunological haemolysis	a)5 b)4	a)2 b)1	a)-3 b)-3						
TACO	4	1	-3				0	1	+1
TRALI	1	0	-1				2	1	-1
TTBI	1	0	-1	2	1	-1			
Anaphylaxis/hypersensitivity	0	1	+1	0	1	+1			
Hypotensive transfusion reaction	0	1	+1						
Other	2	1	-1						

Immunological Haemolysis
a) due to ABO incompatibility
b) due to other alloantibody

Note: no fatalities (IL 2-3) reported in plasma

- Reporting requirements for **fatalities (IL 2-3)** in recipients:
 - Requirements **met** (partially or fully) by **11 out of 11 cases (100%)**

- Pathogen stated in **3 out of 3 TTI cases (2 IL1, 1 IL3)**

NEW!

Common Approach, version 2025: "Concerning reports where a SAR is confirmed to be fatal, any relevant information should be reported in the comments box, such as:
(1) a brief description of patient details (if possible: gender, age, initial illness, clinical indications for transfusion, etc.),
(2) a brief description of the occurrences that led to the fatality. **In the case of a transfusion-transmitted infection, state the pathogen (species) which was demonstrated**
(3) a list of transfused units of blood/blood components; for each unit, any relevant information regarding the preparation of the implicated component(s) (leucodepletion, apheresis...),
(4) the conclusions and follow-up actions (corrective and preventive), if appropriate."

Fatalities (IL 2-3) – Examples

2025 SARE Exercise (2024 data)

Type of BC	Type of Reaction	IL	
RBC	Anaphylaxis/hypersensitivity	2	<p>Patient details: The patient was a 66-year-old man with extensive comorbidities including type II diabetes, hypertension, heart disease with prior aortic valve replacement for endocarditis, previous stroke, COPD, chronic alcoholism, and active smoking. He was admitted for severe gastrointestinal bleeding causing anaemia (Hb 72 g/L), for which one RBC unit was prescribed.</p> <p>Events leading to the fatality/Investigation: Immediately upon starting the transfusion, within the first millilitre, the patient developed acute airway obstruction with facial edema, macroglossia, and respiratory distress, progressing rapidly to cardiorespiratory arrest despite emergency airway management and rescue tracheostomy. Compatibility testing and donor history revealed no abnormalities, and the patient had been transfused previously without adverse reactions. Post-mortem biomarkers showed histamine >100 nmol/L and tryptase 10.1 µg/L (below 11 µg/L but above the 95th percentile of 8.4 µg/L) which support a severe anaphylactic-like reaction as the likely cause of fatal hypoxia.</p> <p>Transfused units and component details: Only one unit of leukoreduced packed RBC was transfused, sourced from a regular donor with no medications and no previous adverse reactions reported from other donations.</p> <p>Root Cause/Conclusions: The fatality is consistent with a probable severe anaphylactic transfusion reaction leading to refractory airway obstruction and hypoxia.</p>
	Other (DHTR)	3	<p>Patient details: The patient was a 23-year-old with homozygous sickle cell disease, a history of multiple vaso-occlusive crises, acute chest syndrome, cerebral vasculopathy, cholecystitis, osteomyelitis, and a previous delayed haemolytic transfusion reaction (no antibodies identified). He was receiving hydroxyurea, voxelator, and had recently completed rituximab therapy; two phenotyped, matched RBC units were transfused before planned stem cell transplantation.</p> <p>Events leading to the fatality/Investigation: From day 5 post-transfusion, the patient developed a vaso-occlusive crisis with laboratory signs of haemolysis (no new antibodies identified), then on day 6 experienced renal failure with acidosis and severe hyperkalaemia, respiratory failure with bilateral pulmonary involvement, and cardiogenic shock, with worsening haemolysis and renal failure and Hb falling to 50 g/L. On day 7, a sudden haemodynamic collapse occurred with severe hypotension; echocardiography showed acute pulmonary heart with LV systolic failure, and the patient died in multivisceral failure despite maximal resuscitation. No new alloantibodies were detected, and compatibility testing did not reveal abnormalities.</p> <p>Transfused units and component details: Two units of phenotyped, antigen-matched, leukoreduced RBCs were transfused, each preceded by a blood exchange.</p> <p>Root Cause/Conclusions: The clinical course is consistent with a severe delayed haemolytic transfusion reaction (DHTR) with hyperhaemolysis, complicated by renal failure, acute chest syndrome-like manifestations, right-heart failure, and multivisceral collapse.</p>

Fatalities (IL 2-3) – Examples

2025 SARE Exercise (2024 data)

Type of BC	Type of Reaction	IL	
RBC	TACO	2	<p>Patient (M, 84 years): HISTORY: - Patient known by palliative support team: AML (Acute Myeloid Leukemia) + aortic valve stenosis.</p> <p>SYMPTOMS REACTION: - General malaise (palliative; AML) - Hypertension: before transfusion 162/66, after 15' 173/81, stop transfusion at 12:21 213/86 - Temp: before transfusion 37°C, after 15' 36.9°C, stop transfusion 37.8°C + SHIVERING - Shivering fever again in the evening: temp at 18:00: 38.2°C and 19:25 38.4°C - At 20:00: oxygen administration (sat 87%) - At 20:45: patient deceased</p> <p>DIAGNOSIS: - Still haemolysis? Acute pulmonary edema? Due to underlying disease?</p>
RBC	Hypotensive transfusion reaction	2	<p>Female (80 years old) had acute bleeding and also suspected to have septic shock. Patient died less than 24 hours from the transfusion. Patient's IgA levels were found to be normal. Microbial culture was performed on the remains of the red blood cell unit and there was no growth. It is unlikely that the patient's symptoms were due to contaminated RBC unit.</p>

Serious Adverse Events

25 Countries:

AT, BE, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IE, IT, LV, LU, NL, NO, PL, PT, RO, SK, SI, ES, SE
and UK(NI)

(No SAE from BG, IS and LT)

Denominator used:

- Total Number of Units Processed
- 24.4 million (2023: 23.7 million)



SAE=4 764

(2023: 2 294; n=26; **108% increase** in 2024 primarily driven by RO's new data)



Serious Adverse Events

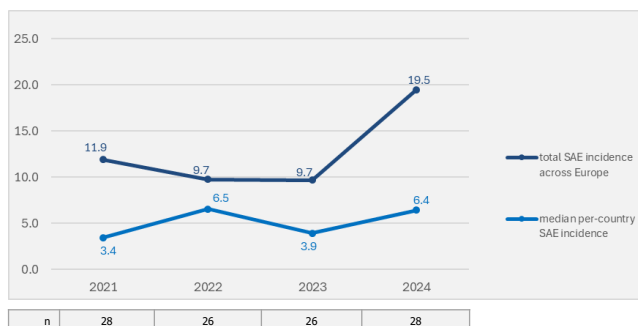
- Annual trends (2021 – 2024)
- Geographic distribution
- Country specific trends (2023 vs. 2024)
- Overview of SAE by activity step
- Annual trends (2021 – 2024) by specification/type of event
- Overview of SAE by type of event



Annual Trends SAE Incidence (total and median)

2025 SARE Exercise (2024 data)

(per 100 000 units processed)



Note1: two complementary metrics: (1) the total SAE incidence per 100 000 units of blood/BC processed, and (2) the median of country-specific SAE incidence rates (per 100 000 units processed) across all reporting countries.

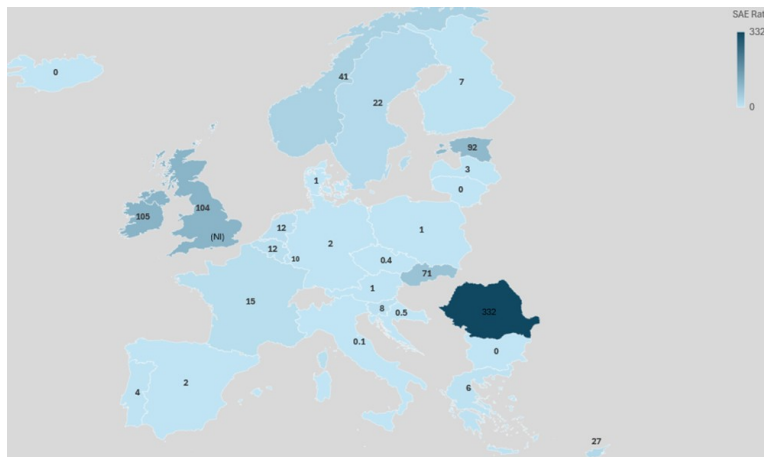
Total SAE is calculated using all reported cases as the numerator and the sum of all reported units processed (including countries reporting zero SAE) as the denominator. Countries not reporting denominator data but reporting SAE contribute to the numerator but not the denominator. Please refer to the denominator completeness table (Annex) for coverage details.

Note2: only countries that reported both SAE cases (including zero) and the number of units processed were included in the median per-country SAE incidence calculations

SAE Incidence rates

2025 SARE Exercise (2024 data)

(per 100 000 units processed)



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Comment RO: *“In 2023, there were limitations in our reporting system that led to underreporting or incomplete documentation of events. For this reason, “N/A” was indicated for that year.*

Starting in 2024, we implemented a revised SAE reporting protocol, along with additional training sessions for personnel involved in the identification and reporting of adverse events.

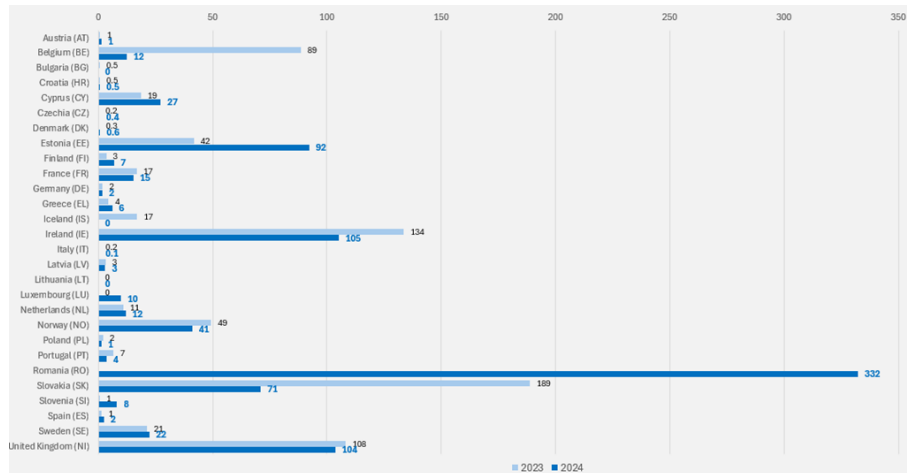
The reporting criteria have been broadened to include cases previously considered minor or ambiguous, in alignment with updated haemovigilance recommendations.”

Comment EL: *“Due to the centralization of blood components process in the province of Attica, which began in April 2024 at the National Blood Centre (EKEA), no production data has been submitted beyond the first quarter of 2024 in the haemovigilance department of EODY. This accounts for the lower figures.”*

SAE Incidence rates

2025 SARE Exercise (2024 data)

(per 100 000 units processed); comparative data 2023 - 2024



Comment RO: “In 2023, there were limitations in our reporting system that led to underreporting or incomplete documentation of events. For this reason, “N/A” was indicated for that year.

Starting in 2024, we implemented a revised SAE reporting protocol, along with additional training sessions for personnel involved in the identification and reporting of adverse events.

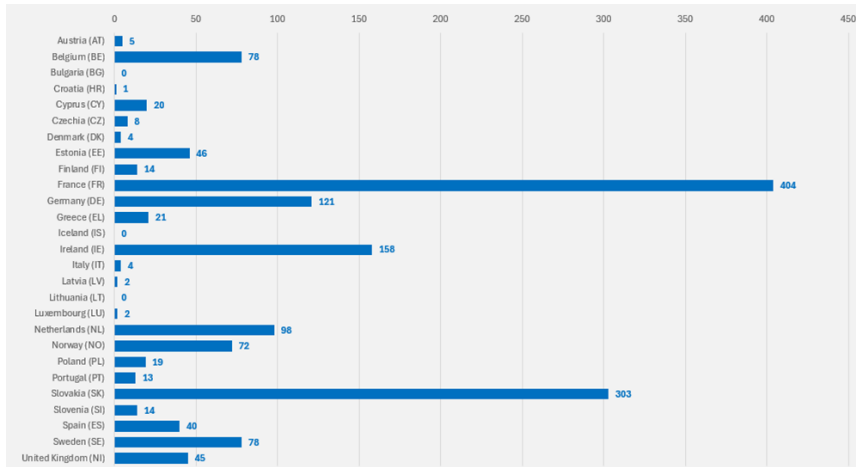
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Total SAE by country

2025 SARE Exercise (2024 data)

Absolute numbers

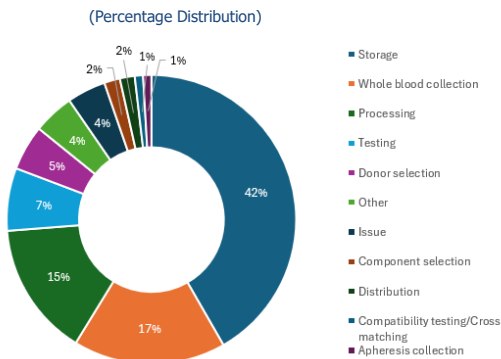


Note: for visualization purposes, RO (3 194) value is not shown above

Comment EL: “Due to the centralization of blood components process in the province of Attica, which began in April 2024 at the National Blood Centre (EKEA), no production data has been submitted beyond the first quarter of 2024 in the haemovigilance department of EODY. This accounts for the lower figures.”

SAE by Activity Step (Category)

2025 SARE Exercise (2024 data)



Activity Step	2023 position	# SAE 2024 (+/- 2023)
Storage	2	1 987 (+1 621) ⚠
Whole blood collection	4=	812 (+621)
Processing	7	715 (+620)
Testing	5	334 (+196)
Donor selection	4=	241 (+55)
Other	1	218 (-622)
Issue	3	206 (+1)
Component selection	6	84 (-25)
Distribution	9=	79 (+21)
Compatibility testing/Cross matching	8	44 (-20)
Apheresis collection	9=	44 (+2)
TOTAL	-	4 764 (+2 470)

Note1: the category Other refers, as per the Common Approach, to any other activity or parameter in the process that can affect the quality and safety of the component that may harm a patient.

Any entry stating "Other" as well as free text was considered "Other" (for more details see the next slide)

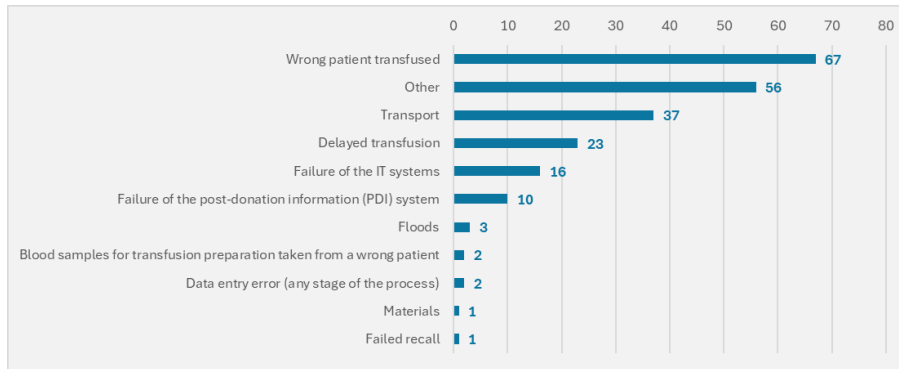
Note2: abbreviations: Component selection (BE or HBB activity step), Compatibility testing/Cross-matching (BE or HBB activity step) and Issue (BE or HBB activity step)

Comment NL: "Whether it was a whole blood or apheresis collection is not clear in these 89 whole blood collection cases."

SAE classified by Activity Step 'Other' - explained

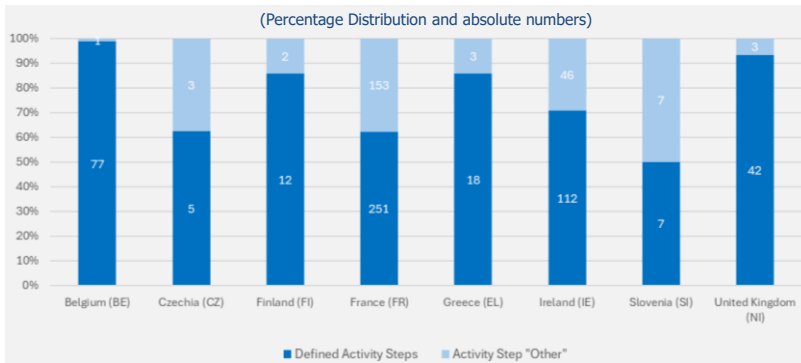
2025 SARE Exercise (2024 data)

Absolute numbers



SAE classified by Activity Step 'Other' vs Defined Steps by country

2025 SARE Exercise (2024 data)

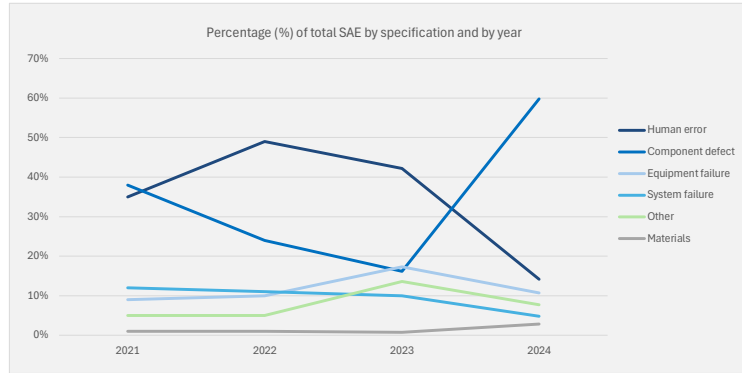


Country	'Other' Proportion (%)		Trend
	2023	2024	
Belgium (BE)	89	1	↓
Cyprus (CY)	15	0	↓
Czechia (CZ)	0	38	NEW
Finland (FI)	0	14	NEW
France (FR)	41	38	↓
Germany (DE)	60	0	↓
Greece (EL)	15	14	↓
Ireland (IE)	21	29	↑
Italy (IT)	40	0	↓
Norway (NO)	1	0	↓
Poland (PL)	40	0	↓
Slovakia (SK)	5	0	↓
Slovenia (SI)	0	50	NEW
Spain (ES)	13	0	↓
United Kingdom (NI)	14	7	↓

Comment DE: "In previous years, all cases of PDI were reported under the category "Other". For 2024, only those PDIs were reported that were either known to the donor at the time of donation but were not reported or not asked about, OR were not yet known at the time of donation but could have affected the quality of donations made further back (e.g. Lyme disease). This time the report was not made under category "Other" but under the categories "whole blood collection" or "apheresis collection". PDIs about acute infections after donation were only reported if the necessary product block or recall was not implemented."

Annual Trends SAE by Type of Event
(Specification)

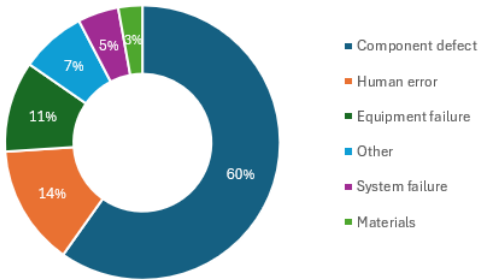
2025 SARE Exercise (2024 data)



SAE by Type of Event

2025 SARE Exercise (2024 data)

(Percentage Distribution)



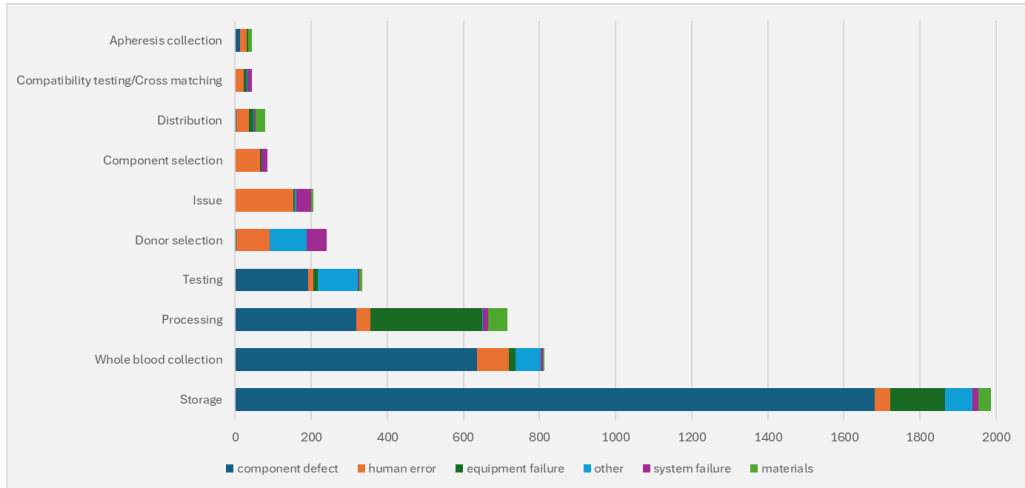
Type of Event	2023 position	# SAE 2024 (+/- 2023)
Component defect	3	2 848 (+2 477) ⚠
Human error	1	675 (-293)
Equipment failure	2	510 (+113)
Other	4	367 (+55)
System failure	5	229 (0)
Materials	6	135 (+118)
TOTAL	-	4 764 (+2 470)

⚠ For more details see Annex ▶

Note: abbreviation Other= "Other (please specify)"

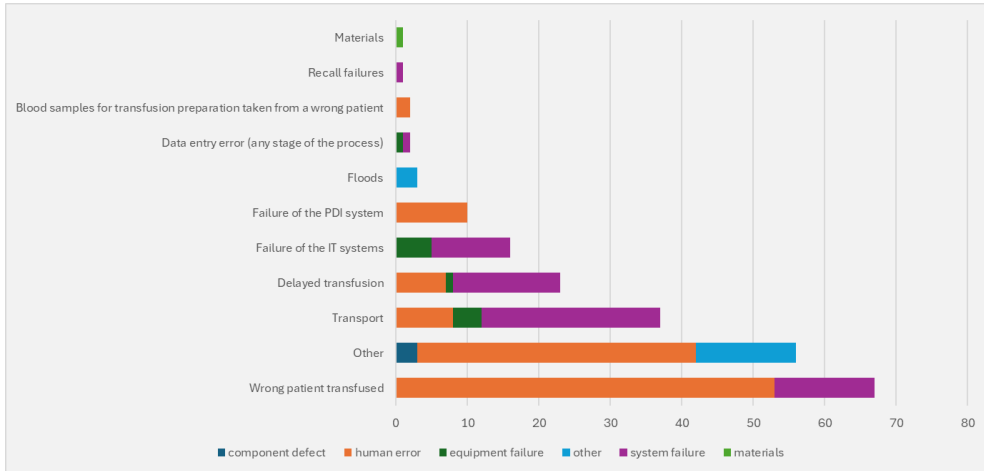
SAE Activity Step by Type of Event

2025 SARE Exercise (2024 data)



SAE Activity Step 'Other' by Type of Event

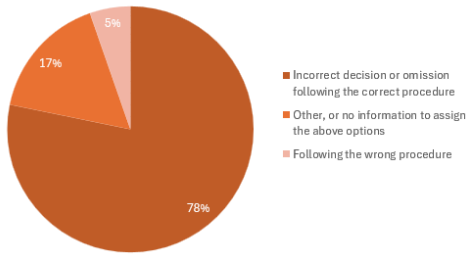
2025 SARE Exercise (2024 data)



SAE reported as 'human error' by type of error

2025 SARE Exercise (2024 data)

(Percentage Distribution)

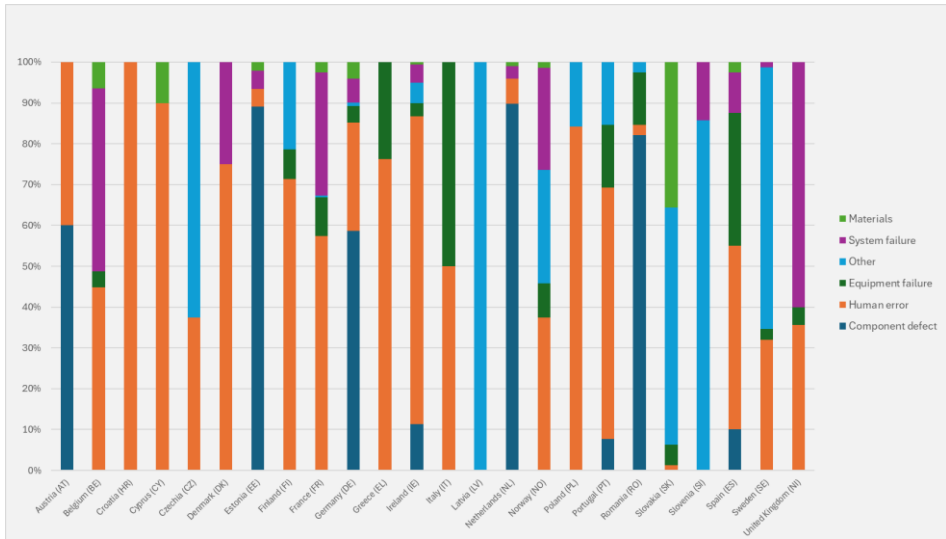


Type of error	2023 position	# SAE 2024 (+/- 2023)
Incorrect decision or omission following the correct procedure	1	528 (-195)
Other, or no information to assign the available options	2	111 (-109)
Following the wrong procedure	3	36 (+11)
TOTAL	-	675 (-293)

SAE by Type of Event and by Country

2025 SARE Exercise (2024 data)

(Percentage Distribution)



Note: abbreviation: Other= "Other (please specify)"

Serious Adverse Reactions (in Donors)

23 Countries:

AT, BE, BG, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LU, NL, NO, PL, PT, RO, SK, SI and SE
(No SAR in donors from HR, LV, LT and UK(NI))

Denominator used:

- Total Number of Whole Blood / Apheresis Collections
- 15.7 million (2023: 16.1 million) / 7.6 million (2023: 7.3 million)

SAR= 2 260

(2023: 3 534; n=22; **36% drop** in 2024, primarily driven by FR's scope update)



Fatalities= 4

(2023: 0)

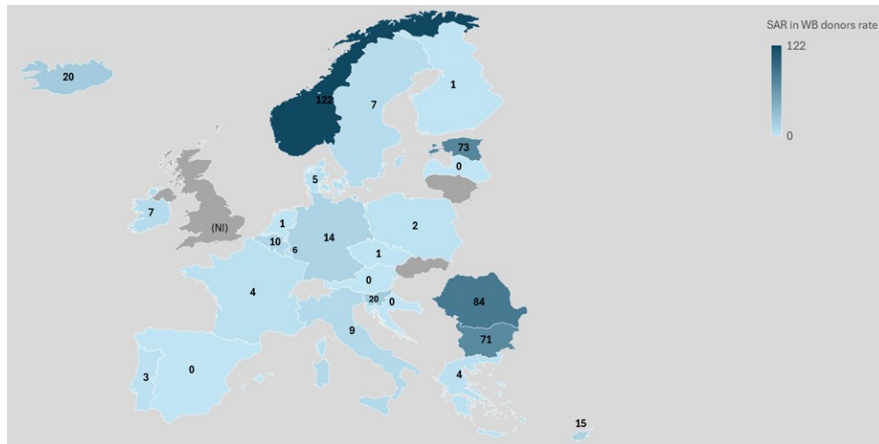


Serious Adverse Reactions (in Donors)

- Geographic distribution
- Overview of SAR in WB donors by type of reaction
- Overview of SAR in apheresis donors by type of reaction
- Fatalities in donors



(per 100 000 WB collections)



Note: LT and SK reported N/A for the number of WB collections, so they appear above in dark grey; UK(NI) reported N/A for the number of SAR, also shown above in dark grey.

Comment FR: “(...)from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 et 2 are notified, traced and analysed at local level of blood establishments). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS. As a result, the number of SARs in donors reported by France for the 2024 calendar year is significantly lower than that of previous years and cannot be compared given the change in the reporting scope.”

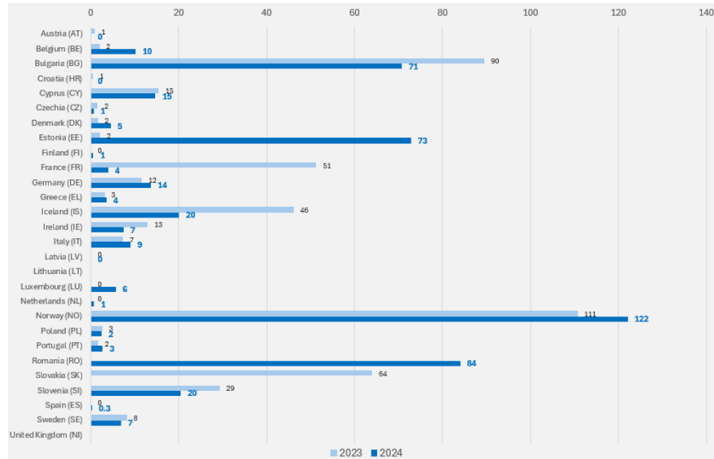
Comment SE: “Data is collected on blood collections but is not distinguished between whole blood or apheresis collection. The reported nr of whole blood collection may include an unknown nr of apheresis collections.”

Comment EL: “There is a misreporting concerning the grade of severity in the above cases.”

SAR in WB Donors Incidence rates

2025 SARE Exercise (2024 data)

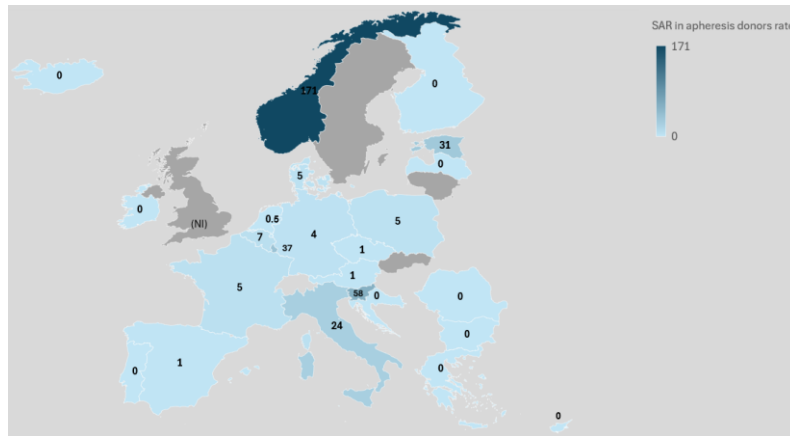
(per 100 000 WB collections); comparative data 2023 - 2024



Note 1: for FR, rates are not comparable due to change in the reporting scope (only grade 3 (severe) and grade 4 (death) reported in 2024 vs all grades in 2023).

Note 2: LT reported N/A for the number of WB collections in both 2023 and 2024. In 2023, RO reported SAR cases but N/A for the number of WB collections. In 2024, SK reported SAR cases but N/A for the number of WB collections. UK(NI) reported N/A for the number of SAR in both 2023 and 2024.

(per 100 000 Apheresis collections)



Note: LT and SK reported N/A for the number of apheresis collections, so they appear above in dark grey; SE and UK(NI) reported N/A for the number of SAR, also shown above in dark grey.

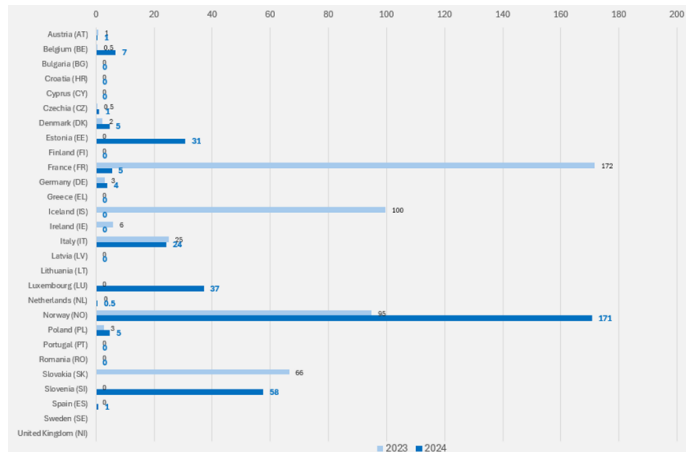
Comment FR: “(...)from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 et 2 are notified, traced and analysed at local level of blood establishments). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS. As a result, the number of SARs in donors reported by France for the 2024 calendar year is significantly lower than that of previous years and cannot be compared given the change in the reporting scope.”

Comment SE: “Data is collected on blood collections but is not distinguished between whole blood or apheresis collection. The reported nr of whole blood collection may include an unknown nr of apheresis collections.”

SAR in Apheresis Donors Incidence rates

2025 SARE Exercise (2024 data)

(per 100 000 WB collections); comparative data 2023 - 2024

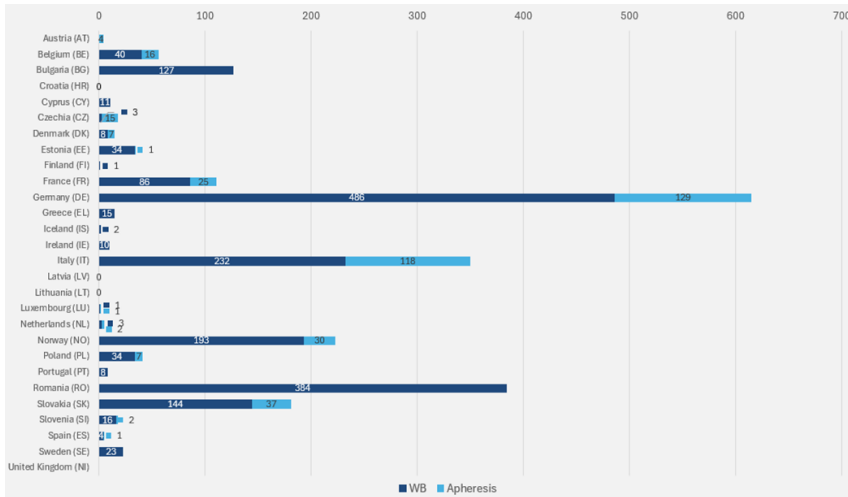


Note 1: for FR, rates are not comparable due to change in the reporting scope (only grade 3 (severe) and grade 4 (death) reported in 2024 vs all grades in 2023).
 Note 2: LT reported N/A for the number of apheresis collections in both 2023 and 2024. In 2024, SK reported SAR cases but N/A for the number of apheresis collections. SE reported N/A for both the number of SAR and the number of apheresis collections in both 2023 and 2024. UK(NI) reported N/A for the number of SAR in both 2023 and 2024.

Total SAR in Donors by country

2025 SARE Exercise (2024 data)

Absolute numbers



Note: UK(NI) reported data N/A.

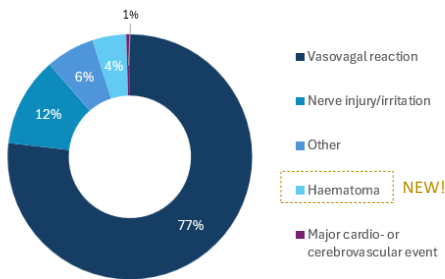
Comment FR: “(...)from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 et 2 are notified, traced and analysed at local level of blood establishments). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS. As a result, the number of SARs in donors reported by France for the 2024 calendar year is significantly lower than that of previous years and cannot be compared given the change in the reporting scope.”

Comment EL: “There is a misreporting concerning the grade of severity in the above cases.”

SAR in WB Donors by Type of Reaction (Specification)

2025 SARE Exercise (2024 data)

(Percentage Distribution)



Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
Vasovagal reaction	1	1 430 (-652)
Nerve injury/irritation	3	220 (-7)
Other	2	120 (-133)
Haematoma (NEW!)	-	83
Major cardio- or cerebrovascular event (CCVE) up to 24hours after donation	4	9 (-2)
General	-	3 (+3)
Allergic reaction	-	0
Citrate reaction	-	0
TOTAL	-	1 865 (-708)

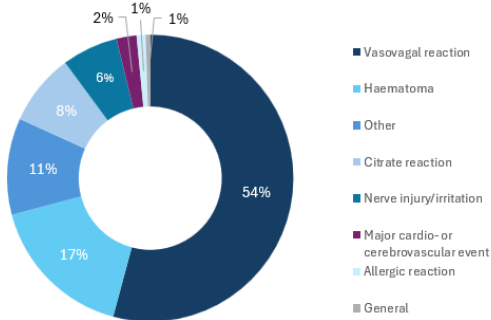
Note1: significant decrease of vasovagal reactions primarily due to update in FR's reporting methodology

Note2: General - (to be filled out only if data for subcategories are not available)

Note3: NEW! Common Approach version 2025, "With regard to the new category of (serious) donor haematoma (added for the 2025 reporting exercise), it should be reserved for donors in whom haematoma was present without (serious) nerve injury/irritation which should be reported under nerve injury/irritation."

SAR in Apheresis Donors by Type of Reaction 2025 SARE Exercise (2024 data) (Specification)

(Percentage Distribution)



Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
Vasovagal reaction	1	214 (-536)
Haematoma (NEW!)	-	66
Other	2	43 (-104)
Citrate reaction	3	32 (+2)
Nerve injury/irritation	4	25 (+4)
Major cardio- or cerebrovascular event (CCVE) up to 24hours after donation	5	9 (+3)
Allergic reaction	6	4 (+1)
General	-	2 (+2)
TOTAL	-	395 (-562)

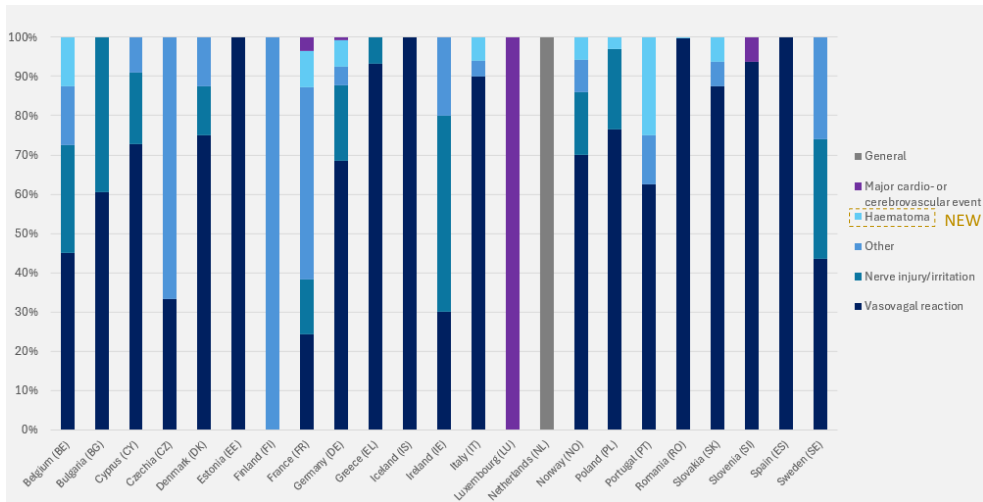
Note1: significant decrease of vasovagal reactions primarily due to update in FR's reporting methodology

Note2: General - (to be filled out only if data for subcategories are not available)

Note3: NEW! Common Approach version 2025, "With regard to the new category of (serious) donor haematoma (added for the 2025 reporting exercise), it should be reserved for donors in whom haematoma was present without (serious) nerve injury/irritation which should be reported under nerve injury/irritation."

SAR in **WB Donors** by Type of Reaction and by Country (Percentage Distribution)

2025 SARE Exercise (2024 data)



Note: AT, HR, LV, LT and UK(NI) reported zero SAR

SAR in WB Donors by Type of Reaction

Absolute numbers; comparative data 2023 - 2024

2025 SARE Exercise (2024 data)

Country	Vasovagal reaction		Absolute Change	Nerve injury/irritation		Absolute Change	Other		Absolute Change	NEW! Haematoma		Major CCVE up to 24h after donation		Absolute Change	General		Absolute Change
	2023	2024		2023	2024		2023	2024		2024	2023	2024	2023		2024	2023	
Austria (AT)							2	0	-2			1	0	-1			
Belgium (BE)	5	18	+13	3	11	+8	0	6	+6	5							
Bulgaria (BG)	68	77	+9	87	50	-37											
Croatia (HR)	1	0	-1														
Cyprus (CY)	9	8	-1	0	2	+2	2	1	-1								
Czechia (CZ)	7	1	-6				0	2	+2								
Denmark (DK)	1	6	+5	0	1	+1	2	1	-1								
Estonia (EE)	1	34	+33														
Finland (FI)							0	1	+1								
France (FR)	1 022	21	*	26	12	*	88	42	*	8	6	3	*				
Germany (DE)	295	333	+38	77	93	+16	63	24	-39	32	3	4	+1				
Greece (EL)	20	14	-6	1	1	0											
Iceland (IS)	4	2	-2				1	0	-1								
Ireland (IE)	6	3	-3	6	5	-1	4	2	-2	N/A	1	0	-1				
Italy (IT)	161	209	+48				27	9	-18	14							
Luxembourg (LU)											0	1	+1				
Netherlands (NL)															0	3	+3
Norway (NO)	135	135		13	31	+18	24	16	-8	11							
Poland (PL)	28	26	-2	4	7	+3	3	0	-3	1							
Portugal (PT)	4	5	+1				1	1	0	2							
Romania (RO)	145	383	+238				16	0	-16	1							
Slovakia (SK)	133	126	-7				13	9	-4	9							
Slovenia (SI)	23	15	-8	1	0	-1											
Spain (ES)	0	4	+4								0	1	+1				
Sweden (SE)	14	10	-4	9	7	-2	7	6	-1								
n	20	20		10	11		14	13		9	4	4			0	1	

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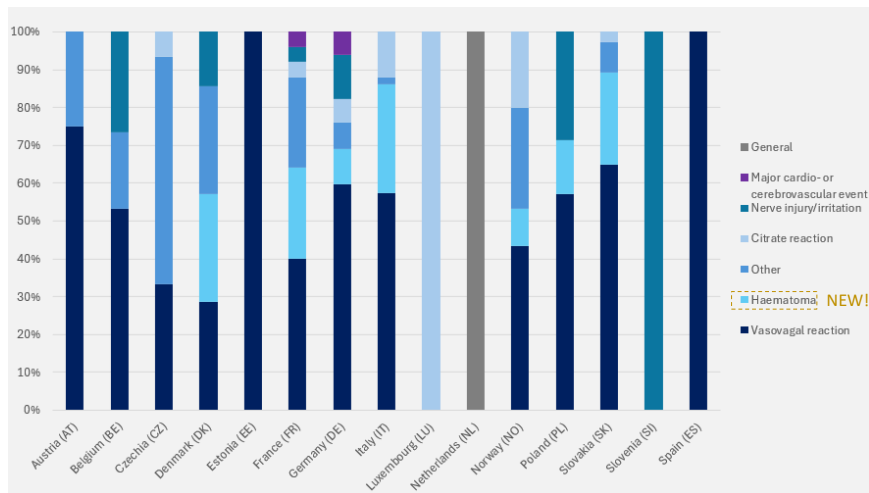


***Comment FR:** “(...)from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 et 2 are notified, traced and analysed at local level of blood establishments). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS. As a result, the number of SARs in donors reported by France for the 2024 calendar year is significantly lower than that of previous years and cannot be compared given the change in the reporting scope.”

Note: in 2023 and 2024, no SAR cases were reported for citrate reactions or allergic reactions

SAR in **Apheresis Donors** by Type of Reaction and by Country (Percentage Distribution)

2025 SARE Exercise (2024 data)



Note: BG, HR, CY, FI, EL, IS, IE, LV, LT, PT, RO and UK(NI) reported zero SAR

SAR in Apheresis Donors by Type of Reaction

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Country	Vasovagal reaction		Absolute Change	NEW!			Citrate reaction		Absolute Change	Nerve injury/irritation		Absolute Change	
	2023	2024		Haematoma	Other	Absolute Change	2023	2024		2023	2024		
			2024	2023	2024								
Austria (AT)	2	3	+1		1	1							
Belgium (BE)	1	8	+7		0	3	+3			0	4	+4	
Czechia (CZ)	7	5	-2		0	9	+9	0	1	+1			
Denmark (DK)	0	2	+2	2	3	2	-1			0	1	+1	
France (FR)	631	10	*	6	41	6	*	6	1	*	4	1	*
Germany (DE)	53	77	+24	12	27	9	-18	4	8	+4	15	15	
Iceland (IS)	1	0	-1										
Ireland (IE)				N/A	1	0	-1						
Italy (IT)	35	66	+31	33	60	2	-58	17	14	-3	0		
Luxembourg (LU)								0	1	+1			
Netherlands (NL)													
Norway (NO)	8	13	+5	3	5	8	+3	3	6	+3	2	0	-2
Poland (PL)	2	4	+2	1	2	0	-2				0	2	+2
Slovakia (SK)	10	24	+14	9	7	3	-4	1	0	+1			
Slovenia (SI)											0	2	+2
Spain (ES)	0	1	+1										
n	10	11		7	9	9		4	6		3	6	

***Comment FR:** “(...)from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 et 2 are notified, traced and analysed at local level of blood establishments). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS. As a result, the number of SARs in donors reported by France for the 2024 calendar year is significantly lower than that of previous years and cannot be compared given the change in the reporting scope.”

SAR in Apheresis Donors by Type of Reaction cont.

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Country	Major CCVE up to 24h after donation		Absolute Change	Allergic reaction		Absolute Change	General		Absolute Change
	2023	2024		2023	2024		2023	2024	
Austria (AT)	2	0	-2						
Belgium (BE)				0	1	+1			
Czechia (CZ)									
Denmark (DK)									
France (FR)	1	1	*						
Germany (DE)	3	8	+5	1	0	*			
Iceland (IS)									
Ireland (IE)									
Italy (IT)				2	3	+1			
Luxembourg (LU)									
Netherlands (NL)							0	2	+2
Norway (NO)									
Poland (PL)									
Slovakia (SK)									
Slovenia (SI)									
Spain (ES)									
Sweden (SE)							N/A	N/A	
	n	3	2	2	2		0	1	

***Comment FR:** “(...)from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 et 2 are notified, traced and analysed at local level of blood establishments). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS. As a result, the number of SARs in donors reported by France for the 2024 calendar year is significantly lower than that of previous years and cannot be compared given the change in the reporting scope.”

Annexes

- Executive Summary (2021-2024)
- Reporting establishments per capita
- Completeness dashboard by metric and country
- SAE Additional Information
- SAR in Donors Additional Information
- SAR (IL 1) (Voluntary)



Parameter	2022 (Data 2021)		2023 (Data 2022)		2024 (Data 2023)		2025 (Data 2024)	
	n	Number	n	Number	n	Number	n	Number
Reporting Countries		30		30		30		28
Reporting Establishments	30	3 307	30	3 346	29	3 244	28	3 190
Blood/BC Units Issued	30	20 633 199	30	21 394 422	30	20 824 019	28	20 467 219
Blood/BC Units Transfused	26	17 808 869	24	17 197 676	23	16 213 234	23	16 478 412
Recipients Transfused*	20	2 912 307	22	3 094 799	20	2 850 968	21	2 998 676
SAR (IL 1) (Voluntary)	23	1 435	21	1 700	21	1 680	20	1 457
SAR (IL 2-3)	24	1 379	27	1 516	25	1 490	25	1 360
Total SAR (IL 2-3) incidence (per 10 ⁵ units transfused)		7.7 [median= 3.7]		8.8 [median= 4.4]		9.2 [median= 3.7]		8.3 [median= 5.2]
Fatalities (IL 2-3) in recipients	11	25	9	27	9	21	5	11
Total Fatalities (IL 2-3) incidence (per 10 ⁵ units transfused)		0.14		0.16		0.13		0.06
Blood/BC Units Processed	28	22 961 648	27	22 943 682	26	23 700 556	28	24 423 977
WB Collections	27	16 242 768	26	15 576 875	26	16 068 007	26	15 679 193
Apheresis Collections	27	6 035 995	26	6 376 960	25	7 286 075	25	7 590 344
SAE	24	2 734	25	2 235	25	2 294	25	4 764
Total SAE incidence (per 10 ⁵ units processed)		11.9 [median= 3.4]		9.7 [median= 6.5]		9.7 [median= 3.9]		19.5 [median= 6.4]
SAR in Donors (Voluntary)	23	2 946	23	2 935	23	3 530	22	2 260
SAR in WB Donors	21	2 262	21	2 271	21	2 573	23	1 865
SAR in Apheresis Donors	15	684	11	664	12	957	15	395
Fatalities in Donors	0	0	0	0	0	0	3	4

n = number of countries reporting

Note1: SAE’s increase in 2024 primarily due to RO’s new data

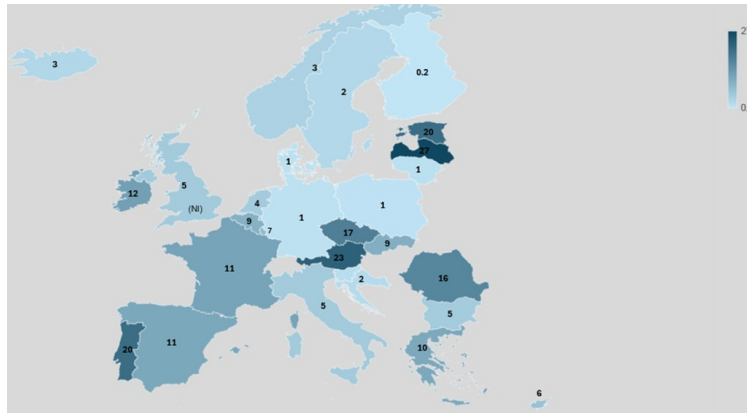
Note2: *recipients transfused was obtained with the sum of number of recipients for each type of BC (i.e. WB, RBC, platelets and plasma) from countries which reported per type of BC plus the number of recipients from countries which only reported the overall number (i.e. regardless of type of BC)

Note3: *for 2024 the value was obtained with the sum of number of recipients for each type of BC (i.e. WB, RBC, platelets and plasma) from 19 countries (3 219 912) plus the number of recipients from EE and EL (132 307) which only reported the overall number (i.e. regardless of type of BC)

Reporting Establishments per capita

2025 SARE Exercise (2024 data)

(per 1 million population (pmp))



population as 1st January Y+1, <https://ec.europa.eu/eurostat/>

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Note: small drop for PT and SK in comparison with 2023 (26 and 13, respectively).

Comment PT: “At the end of 2024, all the institutions that had not performed any type of activity (collection, analysis, processing, distribution, issue or transfusion) of blood or blood components, in the last 3 years, were removed from the database, after being previously questioned.”

Comment SK: “Reason for the sudden drop is consolidation of transfusion establishments with blood banks; most transfusion establishments now have their own integrated blood banks. This means that instead of submitting two separate reports, they now submit a single combined annual report.”

Completeness Dashboard by metric and country

2025 SARE Exercise (2024 data)

Country	General completeness				Number of Recipients regardless of BC	Component level completeness										Number of Collections - Denominator available for SAE incidence (a Denom?)		
	% Reports Received	% Number of Units Issued	% Number of Recipients	% Number of Units Transfused		Units Issued				Units Transfused				Denominator available for SAE (IL 2-3) incidence?	Units Processed - Denominator available for SAE incidence?	WB	Apheresis	
						WB	RBC	Platelets	Plasma	WB	RBC	Platelets	Plasma					
Austria (AT)	88	100	99	100	N/A	Yes (0)	Yes	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Belgium (BE)	100	100	100	100	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bulgaria (BG)	99	99	99	99	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Croatia (HR)	100	100	99	99	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cyprus (CY)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Czechia (CZ)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Denmark (DK)	100	100	100	100	Yes	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes, but incomplete	Yes	Yes	Yes
Estonia (EE)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Finland (FI)	100	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes (0)	N/A	N/A	N/A	Yes (0)	No	Yes	Yes	Yes	Yes
France (FR)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Germany (DE)	99	N/A	N/A	N/A	N/A	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes, but incomplete	Yes	Yes	Yes
Greece (EL)	87	87	87	87	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ireland (IE)	100	100	100	100	N/A	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes
Italy (IT)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Latvia (LV)	100	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	No	No	No
Lithuania (LT)	100	100	N/A	N/A	N/A	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	Yes	Yes	Yes
Luxembourg (LU)	100	100	100	100	Yes	Yes (0)	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes, but incomplete	Yes	Yes	Yes
Netherlands (NL)	94	100	77	100	N/A	Yes (0)	Yes	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Norway (NO)	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Poland (PL)	100	100	100	100	N/A	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	Yes	Yes	Yes
Portugal (PT)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Romania (RO)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Slovakia (SK)	78	82	N/A	79	N/A	Yes	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes, but incomplete	Yes	No	No
Slovenia (SI)	100	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	Yes	Yes	Yes
Spain (ES)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sweden (SE)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
United Kingdom (UK)	100	100	99	100	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Note1: HU, MT and LI did not report in 2024.

Note2: N/A- data not available; Yes(0)- country reported 0 units.

SAE Additional Information

Specification	SAE Examples/Comments	# SAE
Component defect 60% (2 848 out of 4 764)	• No additional information provided	2 626
	• Platelet units found to have positive bacterial screening after "negative to date" distribution, the units from the donations had already been transfused	88
	• PDI that was known at the time of donation but not mentioned by the donor OR information that led to the donor's refusal but may have influenced the quality of former donations (e.g. newly diagnosed malignant disease or <i>Borellia</i> infection)	58
	• Non available information (N/A)	15
	• Repeat donor tested positive for HCV	14
	• Insufficient deferral period after risk of infection due to incorrect programming in EDP	3
	• Non available information (N/A)	129
	• No additional information provided	101
	• Wrong patient transfused , resulting from a combination of multiple successive failures during the same BC prescription process. The failures are combined from the error of identity of patient in prescribing BCs, failures of communication between the staff taking care of the patient and the staff issued BCs, the error in checking of identity patient in issuing of these BCs in the BE or in the HBB, the error in checking of identity patient in the clinical area (at the reception of BCs and/or at bedside). 10% occurred in urgent settings, none occurred during night shifts (8 PM to 8 AM); 16% occurred during week-end or public holidays. When a SAR ABO incompatibility results from a 'wrong patient transfused', they are not included in this category. They are reported only as SAR ABO incompatibility.	67
	• Most reported SAEs were related to unreported recent travel to malaria- or Chagas-endemic areas, largely due to donor omission and insufficient emphasis during the pre-donation interview, although no TTIs occurred and all post-donation testing was negative. Less frequently, procedural omissions (such as missed Hb testing or shortened inter-donation intervals) were reported, none of which resulted in adverse consequences, and all events were followed by systematic reminders of existing procedures.	30
• Donor accepted despite info for exclusion; insufficient donor deferral	26	
• Delayed transfusion (DT) , resulting from a combination of multiple successive failures during the same BC prescription process. The failures are combined from the delay in prescribing BCs, failures of communication between the staff taking care of the patient and the staff issuing BCs, the delay in issuing these BCs, the delay in their transport/shipment from the BE or from the HBB to the transfusion healthcare area and the delay in the transfusion procedure. This DTs occur mainly in urgent settings (20%) and in non-urgent settings (medical and intensive care units 12%, emergency department 13% and obstetrics 4%. And among DTs in urgent settings, 3% occurred during night shifts (8 PM to 8 AM).	23	
Human error 14% (675 out of 4 764)	• Lack of concentration	20
	• Overcollection due to plasma bag not hanging freely (2), doctor mistakenly prescribed too large collection volume(5), overcollection due to incorrect setting on device (6)	13
	• Transfusion/Issue of incorrectly labelled component	11
	• Failure of the PDI system: they are due to non-application of procedures. A systematic reminder is carried out for staff who have not respected these procedures	10
	• Transfusion on an invalid sample	10
	• ICBT e.g. due to insufficient or no bedside check	9
	• ICBT due to incorrect product allocation during issue	9
	• WBIT, labelling error, donor mix-up	8
	• Error in blood component transportation	8
	• Wrongful registration of the blood donor	5
	• Incorrect blood component issued by blood bank	5
	• Incorrect labelling after irradiation, Errors during irradiation, omission of quality control	4
	• FFP units which were not transfused to patients returned to HBB by clinic without marked as unsuitable. HBB realized that the specific FFP units were not suitable for transfusion and after preventive and corrective actions the units were discarded.	3
	• Microbe contamination in platelet product (which were not transfused), possibly due to venipuncture step	3



SAE classified by Specification

2025 SARE Exercise (2024 data)

Specification	SAE Examples/Comments	# SAE
Equipment failure 11% (510 out of 4 764)	<ul style="list-style-type: none"> • No additional information provided • These rare SAEs are subject to systematic equipment maintenance check and systematic reminders of the procedures and the need to respect them • Non available information (N/A) 	423
	• Burst blood bag	38
	• Missing or invalid positive controls for infection serology	12
	• Incorrect weight indication on the weigher/mixer resulting in too much blood volume being taken	11
	• IT-software error and machine malfunction	3
	• Inadequate blood typing reagents	2
	• Weld failure	2
	• Incorrect weak D declaration as D negative due to EDP misprogramming	2
	• Omission of alloantibody screening test of donors due to EDP misprogramming	1
	• Overfilling of EC, probably due to defective scale	1
	• The machine drew too much plasma	1
	• No additional information provided	83
	• Positivity ALT during testing	70
	• The donor did not provide correct or full information at the donation	50
	• Collapse during whole blood collection	40
• Covid, Herpes Zoster in donor selection	24	
• Rupture veins during whole blood collection	17	
• Positivity NCT during testing	11	
• The interview form used is inadequate	9	
• Positive viral- or microbiological tests came back after donation	8	
• The transfused component doesn't meet the requirements (incorrect blood antigen determined)	7	
• Leaking pack noted on arrival to hospital x 3, Clots observed in unit x 1, Minor red cell sediment in ports, not significant to transfusion and no patient impact x 1, Leak noted in unit pre-transfusion x 1, Unit haemolysed x 1	7	
• Positivity anti HCV during testing	4	
• Patient hid the information about the therapy he receives/his diagnosis. Blood components were distributed for use	3	
• Extensive floods	3	
• National epidemiological situation changed (increased amount of HEV cases due to sausages); additional blood donation testing was started, and positive cases were found on archive samples; the blood products were already transfused	2	
Other 7% (367 out of 4 764)		

SAE classified by Specification

2025 SARE Exercise (2024 data)

Specification	SAE Examples/Comments	# SAE
System failure 5% (229 out of 4 764)	• Failure of the IT systems/ Transport: these rare SAEs are subject to systematic equipment maintenance check and systematic reminders of the procedures and the need to respect them	36
	• Non available information (N/A)	34
	• Donor eligibility violations	33
	• Delayed transfusion : resulting from a combination of multiple successive failures during the same BC prescription process (...)	15
	• Wrong patient transfused : resulting from a combination of multiple successive failures during the same BC prescription process (...)	14
	• Little knowledge about rules and procedures	12
	• No additional information provided	9
	• Lack of routines/internal procedure	3
	• Stress	3
	• Typing errors when entering positive infection parameters were interpreted as negative by EDP due to poor programming	2
	• BCs issued without specific characteristics - irradiation and/or CMV	2
	• Errors due to delayed process validation	1
	• Different procedure for accepting donor regarding medical declaration form	1
	• Failure to provide irradiated units after introduction of new lab-system	1
• Issue of donor-incompatible plasma for patient with planned kidney transplant	1	
Materials 3% (135 out of 4 764)	• Burst blood bag	49
	• Burst blood bag, plasma chylostasis	33
	• Plasma chylostasis	30
	• Faulty pipette tips or faulty positive controls led to invalid test results	2
	• Non available information (N/A)	1
	• No additional information provided	1
	• Faulty lot number of serological immunoassay cards	1
	• The units were pathogenically reduced but the exposure report had an incorrect date due to a date change in the system	1
	• Wrong result of the phenotype resulting from a default reagent	1
	• False positive results due to faulty reagent lot number	1

SAR in Donors Additional Information

SAR in Donors – Additional information provided

2025 SARE Exercise (2024 data)

Country (# SAR)	WB vs Apheresis Donation	Comments (related to 'Other' and Major CCVE)
Belgium (56)	71% (40) WB 29% (16) Apheresis	<ul style="list-style-type: none"> • WB 'Other' category: 4 thrombophlebitis; 1 tendon-muscle injury; 1 erysipelas • Apheresis 'Other' category: 3 thrombophlebitis
Cyprus (11)	100% WB	<ul style="list-style-type: none"> • 'Other' category: after removing the needle from the donor's arm, the blood flow could not stop, and he was transferred to the Emergency Room of the hospital and later released.
Czechia (18)	17% (3) WB 83% (15) Apheresis	<ul style="list-style-type: none"> • WB 'Other' category: 2 vasovagal reaction with fall and laceration • Apheresis 'Other' category: 3 spasm and hypotension due to replacement of physiological saline and citrate; 1 tissue infection (<i>Str. pyogenes</i>); 2 vasovagal reaction with spasm; 3 vasovagal reaction with fall and laceration
Finland (1)	100% WB	<ul style="list-style-type: none"> • 'Other' category: 28 hours after whole blood donation, donor experienced chest pain during strenuous labour, which resulted in hospitalisation, myocardial infarction and operation (balloon angioplasty with stent) and diagnosing of coronary artery disease. The donor had been without cardiac symptoms before the event and had been in follow-up due to high cholesterol levels. Blood donation and the resulting dehydration and lowered haemoglobin may have been contributing factors leading to the cardiovascular event. The donor's coronary artery disease had probably been developing for a long time but was asymptomatic and undiagnosed. <p>Seriousness: Serious; Severity: Grade 3 (classified using the AABB Severity Grading Tool of Blood Donor Adverse Events: category E; acute cardiac symptoms; myocardial infarction -> diagnosis medically confirmed); Imputability: 1/possible</p>
Germany (615)	79% (486) WB 21% (129) Apheresis	<ul style="list-style-type: none"> • WB 'Other' category: 9 thrombophlebitis; 1 inflammatory tissue reaction; 1 phlegmon; 7 venous thrombosis; 1 pseudoaneurysm; 1 allergic reaction; 1 unclear neurological symptoms; 1 cerebral seizure; 1 anaemia; 1 traffic accident after donation • Apheresis 'Other' category: 2 thrombophlebitis; 1 phlegmon; 1 cyst formation in the crook of the elbow; 3 haemolysis; 1 unclear neurological symptoms; 1 status epilepticus
Italy (350)	66% (232) WB 34% (118) Apheresis	<ul style="list-style-type: none"> • WB 'Other' category: 5 post-donation accident-related head trauma and 4 thrombophlebitis • Apheresis 'Other' category: 2 thrombophlebitis
Luxembourg (2)	50% (1) WB 50% (1) Apheresis	<ul style="list-style-type: none"> • A donor presented for WB donation, filled in the pre-donation questionnaire and got a medical consultation before the donation. No contraindication for a blood donation was detected (normal physiological parameters, negative answer on exceptional bleedings). A bag of WB had been collected without any problems. By performing the hemogram, the laboratory technician found on the same day a haemoglobin result of 6.5 g/L. He was immediately informed by the BTC about the result and said that he was in a good shape and had not detected any fatigue. During the phone call, he said that he has slight bleeding due to haemorrhoids since approximately 1 year. He was informed to contact as soon as possible his treating medical doctor. He did a consultation at an emergency department, got two blood transfusions of RBC. Unfortunately, we are unaware of the etiology.

Country (# SAR)	WB vs Apheresis Donation	Comments (related to 'Other' and Major CCVE)
Netherlands (5)	no distinction can be made based on donation type	'Other' category: 4 vasovagal reactions and 1 venipuncture related/thrombophlebitis
Norway (223)	87% (193) WB 13% (30) Apheresis	<ul style="list-style-type: none"> WB 'Other' category: 1 local allergic reaction; 6 other systemic reactions, 9 reactions with local pain in the arm not judged to be due to nerve irritation Apheresis 'Other' category: 6 local pain reactions not judged to be due to nerve irritation; 2 systemic reactions
Portugal (8)	100% WB	'Other' category: 1 brachial artery pseudoaneurysm
Slovenia (18)	89% (16) WB 11% (2) Apheresis	WB: 1 Major CCVE up to 24 hours after donation: The donor suffered an acute myocardial infarction in the evening around 11 pm. The imputability assessment: probably, likely
Sweden (23) (2 cases from 2023)	(23) WB N/A Apheresis	WB 'Other' category: 3 artery puncture; 3 skin reaction and received antibiotics

SAR in Donors – Additional information provided

2025 SARE Exercise (2024 data)

Country (# SAR)	SAR Rate (calculated by country)	SAR by Gender	Type of Donor	WB vs Apheresis Donation	Comments
France (111)	4.2 SARs per 100 000 donations (2 650 837 donations) or 0.7 SARs per 10 000 blood donors (1 557 675 donors)	75% in women vs 25% in men	85% regular blood donors vs 15% first-time blood donors (regardless of inclusion criteria)	77% (86) WB 23% (25) Apheresis 45% occurred in fixed site of BE vs 55% in mobile collection site	<ul style="list-style-type: none"> WB Major CCVE event (3 SAR): 2 superficial vein thrombosis, 1 deep vein thrombosis. All occurred in current women donors WB 'Other category': 18 iron deficiencies, 16 anaemia, 2 arterial punctures, 2 tendon injuries, 1 arteriovenous fistula, 1 local infection, 1 lymphangitis and 1 uncategorised complication of donation (atypical chest pain) Apheresis Major CCVE (1 SAR): 1 superficial vein thrombosis, occurred in a current male donor Apheresis 'Other category': 3 lymphangitis, 1 anaemia, 1 iron deficiency, 1 tendon injury
Ireland (10) (2 from 2022, 2 from 2023 and 6 from 2024)	133 996 attempted WB donations and 8 339 attempted apheresis donations in the calendar year 2024 (total of 142 335 attempted donations). The rate of SARs for WB and apheresis donations was therefore 1 in 14 234 attempted donations.	5 donors are female and 5 are male		100% WB	<ul style="list-style-type: none"> 3 SARs classified as vasovagal reactions, 1 was an immediate vasovagal reaction without injury, 2 were delayed vasovagal reactions with injury. <ul style="list-style-type: none"> The immediate vasovagal reaction occurred in a 46-year-old male donor with a history of 8 previous donations. He briefly lost consciousness for about 2 minutes. During this period, he appeared to stop breathing and had no detectable pulse, prompting clinic staff to start CPR and use a portable AED. The AED detected electrical activity (no shock advised), and the donor quickly regained consciousness. He was transported to hospital where tests confirmed there was no cardiac arrest. The donor recovered completely, was discharged the next morning, and advised to follow up with his GP. He is now permanently excluded from donating blood. The two donors who had delayed vasovagal reactions were regular female donors; one was 51 years of age and was unconscious for > 60 seconds without seizure-like activity or incontinence; the second donor was 61 years of age and was unconscious for < 60 seconds and did not have seizure-like activity or incontinence. Both donors were admitted to hospital for overnight observations. The 51-year-old donor received 3 litres of intravenous fluid due to hypotension. Both donors made a full recovery and are permanently excluded from donating. 5 SARs classified as nerve injury/nerve irritation, 4 of these were nerve injuries on needle insertion and 1 was a nerve irritation. Symptoms lasted longer than 12 months in all 5 cases. 'Other' category: 2 cases of painful arms, in both donors, symptoms persisted for more than 12 months after donation.

SAR (IL 1)
(Voluntary)

Total SAR (IL 1) and Fatalities (IL 1) by Type of BC

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Total Number of SAR (IL 1)	2023	2024	% Change
RBC	1 190	1 092	-8
Platelets	252	194	-23
Plasma	161	100	-38
MTOC	77	71	-8
WB	0	0	-
TOTAL	1 680	1 457	-13

n (RBC)	20	19
n (Platelets)	17	13
n (Plasma)	11	11
n (MTOC)	7	9
n (WB)	0	0

Total Number of Fatalities (IL 1)	2023	2024	Absolute Change
RBC	16	14	-2
Platelets	5	3	-2
Plasma	0	1	+1
MTOC	1	3	+2
WB	0	0	-
TOTAL	22	21	-1

n (RBC)	4	5
n (Platelets)	2	3
n (Plasma)	0	1
n (MTOC)	1	3
n (WB)	0	0

Total SAR (IL 1) by Type of Reaction

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
FNHTR	2	484 (-10)
Anaphylaxis/hypersensitivity	1	445 (-204)
Other	3	200 (+15)
TACO	4	150 (-11)
TAD	5	59 (-4)
Immunological haemolysis	8	40 (+15)
TRALI	7	39 (+5)
Hypotensive transfusion reaction	10	18 (+10)
TTBI	9	12 (-3)
PTP	12=	6 (+5)
Non-immunological haemolysis	6	3 (-36)
TTVI	11	1 (-4)
TTPI	12=	0 (-1)

Total SAR (IL 1) - TTI

2025 SARE Exercise (2024 data)

Absolute numbers; comparative data 2023 - 2024

Absolute numbers; by type of BC

Type of TTI	2023	2024	Absolute Change
TTBI	15	12	-3
TTVI	5	1	-4
TTPI	1	0	-1
TOTAL	21	13	-8

n (TTBI)	1	2
n (TTVI)	2	1
n (TTPI)	1	0

Type of TTI	RBC			Platelets			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
TTBI	7	7	0	7	4	-3	1	1	0
TTVI	2	1	-1	3	0	-3			
TTPI	1	0	-1						
TOTAL	10	8	-3	10	4	-6	1	1	0

Note1: zero TTFI and TTPRI cases reported in both 2023 and 2024.

Note2: zero TTIs reported in plasma or WB in both 2023 and 2024.

Note3: TTBI- RBC- *Serratia marcescens et Proteus mirabilis (1), Yersinia enterocolitica (1), Bacillus cereus (1), Streptococcus mitis and Streptococcus oralis (1), Klebsiella oxytoca, E. coli and Staphylococcus haemolyticus (3)*; Platelets- *Staphylococcus warneri (1), Staphylococcus hominis and Staphylococcus epidermidis (1), Bacillus cereus (1), Streptococcus dysgalactiae (1)* ; MTOC- *Staphylococcus aureus (1)*

TTVI- RBC- HEV (1)

Total Fatalities (IL 1) by Type of Reaction, Type of BC and Country

2025 SARE Exercise (2024 data)

Fatalities (IL 1) = 21

Absolute numbers

Type of Reaction	2023	2024	Absolute change
TACO	7	8	+1
Anaphylaxis/hypersensitivity	3	4	+1
Other	2	2	0
TTBI	2	2	0
Immunological haemolysis due to other alloantibody	4	1	-3
TRALI	1	1	0
Hypotensive transfusion reaction	0	1	+1
TAD	0	1	+1
Non-immunological haemolysis	3	1	-2

7 Countries Reporting: BE, FI, FR, DE, NL, PL, PT

Country (#)	RBC	Platelets	Plasma	MTOC
Belgium (3)	2		1	
Finland (2)	1			1
France (2)	2			
Germany (8)	7	1		
Netherlands (3)	2			1
Poland (2)		1		1
Portugal (1)		1		

RBC	TTBI	A 64-year-old patient with HIV/AIDS in a severely reduced and highly unstable general condition, septic after transfemoral amputation, and additionally pneumogenic sepsis developed after transfusing of 2 ECs pulmonary oedema and an increase in catecholamine requirement (already previously 4mg arterenol/hour). Development of lactic acidosis and progressive drop in blood pressure until resuscitation was necessary. Resuscitation ultimately unsuccessful - exitus lethalis. An EC showed rapidly growing <i>Yersinia enterocolitica</i> . A contamination of the EC due to reflux of the patient's blood was discussed, however, a possible causality cannot be ruled out here due to the temporal relationship of the transfusion and the deterioration.
Platelets		A 63-year-old patient with newly diagnosed B-cell lymphoma received two pool TCs preoperatively before port placement due to thrombocytopenia. About an hour later, dyspnoea, a rise in temperature and septic shock occurred. <i>Bacillus cereus</i> was found in the blood cultures, as well as in one of the pool TCs. The patient died the next day as a result of the sepsis despite antibiotic treatment. A comparative antibiotic resistance test or sequencing of the bacterial DNA was not carried out.

Next step



- 2025 SARE exercise (data 2024) FINAL REPORT

SARE-BLOOD@edqm.eu

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